

1 THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL :
5 PRESCRIPTION OPIATE : MDL NO. 2804
6 LITIGATION :

7 : CASE NO.
8 THIS DOCUMENT : 1:17-MD-2804
9 RELATES TO ALL CASES: Hon. Dan A. Polster

10 - - -
11 Thursday, April 25, 2019

12 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
13 CONFIDENTIALITY REVIEW

14 - - -
15 Videotaped deposition of DAVID A.
16 KESSLER, M.D. (Day 1), taken pursuant to
17 notice, was held at Baron & Budd, 600 New
18 Hampshire Avenue NW, Floor G, Washington, DC
19 20037, beginning at 9:28 a.m., on the above
20 date, before Lisa V. Feissner, RDR, CRR, Notary
21 Public.

22 - - -
23 GOLKOW LITIGATION SERVICES
24 877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

1 APPEARANCES:

2 LEVIN PAPANTONIO THOMAS MITCHELL
3 RAFFERTY & PROCTOR PA
4 BY: TROY A. RAFFERTY, ESQUIRE
5 316 South Baylen Street - Suite 600
6 Pensacola, Florida 32502
7 (850) 435-7163
8 trafferty@levinlaw.com
9 -- Representing Plaintiffs

10 SEEGER WEISS LLP
11 BY: PARVIN K. AMINOLROAYA, ESQUIRE
12 BY: KSENIYA LEZHNEV, ESQUIRE
13 77 Water Street - 8th Floor
14 New York, NY 10005
15 212-584-0700
16 paminolroaya@seegerweiss.com
17 klezhnev@seegerweiss.com
18 -- Representing Plaintiffs

19 LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
20 BY: LEXI J. HAZAM, ESQUIRE
21 275 Battery Street - 29th Floor
22 San Francisco, CA 94111-3339
23 (415) 956-1000
24 lhazam@lchb.com
-- Representing Plaintiffs

NAPOLI SHKOLNIK PLLC
BY: HUNTER J. SHKOLNIK, ESQUIRE
360 Lexington Avenue - 11th Floor
New York, NY 10017
(844) 230-7676
hunter@napolilaw.com
-- Representing Cuyahoga County Plaintiffs

SPANGENBERG SHIBLEY & LIBER LLP
BY: PETER H. WEINBERGER, ESQUIRE
1001 Lakeside Avenue East - Suite 1700
Cleveland, OH 44114-1149
(216) 600-0114
pweinberger@spanglaw.com
-- Representing Plaintiffs

1 APPEARANCES: (Continued)

2 MOTLEY RICE LLC

BY: LINDA SINGER, ESQUIRE

3 (via video stream / realtime stream)

401 9th St. NW, Suite 1001

4 Washington, DC 20004

(202) 386-9626

5 lsinger@motleyrice.com

-- Representing Plaintiffs

6

BARON & BUDD P.C.

7 WILLIAM G. POWERS, ESQUIRE

NOAH RICH, ESQUIRE

8 (via video stream / realtime stream)

600 New Hampshire Avenue, NW

9 The Watergate, Suite 10-A

10 Washington, DC 20037

(202) 333-4562

wpowers@baronbudd.com

11 nrich@baronbudd.com

-- Representing Plaintiffs

12

SKIKOS, CRAWFORD, SKIKOS & JOSEPH, LLP

13 BY: MARK G. CRAWFORD, ESQUIRE

(via video stream / realtime stream)

14 One Sansome Street - Suite 2830

San Francisco, California 94104

15 (415) 546-7300

mcrawford@skikos.com

16 -- Representing Plaintiffs

17 LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

BY: MATIAS BUSTAMANTE, ESQUIRE

18 (via video stream / realtime stream)

275 Battery Street - 29th Floor

19 San Francisco, CA 94111

(415) 956-1000

20 mbustamante@lchb.com

-- Representing Plaintiffs

21

22

23

24

1 APPEARANCES: (Continued)

2 MORGAN & MORGAN

BY: EMILY JEFFCOTT, ESQUIRE

3 (via video stream / realtime stream)

700 South Palafox Street - Suite 95

4 Pensacola, FL 32502

(850) 316-9074

5 ejeffcott@forthepeople.com

-- Representing Plaintiffs

6

LEVIN PAPANTONIO THOMAS MITCHELL

7 RAFFERTY & PROCTOR PA

BY: NEIL E. McWILLIAMS, ESQUIRE

8 (via video stream / realtime stream)

316 South Baylen Street - Suite 600

9 Pensacola, Florida 32502

(850) 435-7138

10 nmcwilliams@levinlaw.com

-- Representing Plaintiffs

11

DECHERT LLP

12 BY: HOPE S. FREIWALD, ESQUIRE

Cira Centre

13 2929 Arch Street

Philadelphia, PA, 19104-2808

14 (215) 994-2514

hope.freiwald@dechert.com

15 and

DECHERT LLP

16 ALEJANDRO HERRERA, ESQUIRE

Three Bryant Park

17 1095 Avenue of the Americas

New York, NY 10036-6797

18 (212) 698-3500

alejandro.herrera@dechert.com

19 -- Representing the Purdue Defendants

20 ARNOLD & PORTER KAYE SCHOLER LLP

BY: JOSHUA M. DAVIS, ESQUIRE

21 BY: JOHN CELLA, ESQUIRE

601 Massachusetts Avenue, NW

22 Washington, DC 20001-3743

(202) 942-5743

23 joshua.davis@arnoldporter.com

john.cella@arnoldporter.com

24 -- Representing the Endo and Par Defendants

1 APPEARANCES: (Continued)
2 KIRKLAND & ELLIS LLP
BY: JENNIFER LEVY, ESQUIRE
3 1301 Pennsylvania Avenue, NW
Washington, DC 20004
4 (202) 389-5211
jennifer.levy@kirkland.com
5 and
KIRKLAND & ELLIS LLP
6 BY: MICHAEL LeFEVOUR, ESQUIRE
300 North LaSalle
7 Chicago, IL 60654
(312) 862-3728
8 michael.lefevour@kirkland.com
-- Representing the Allergan Defendants
9
O'MELVENY & MYERS LLP
10 BY: AMY LAURENDEAU, ESQUIRE
610 Newport Center Drive
11 17th Floor
Newport Beach, CA 92660
12 (949) 823-7926
alaurendeau@omm.com
13 and
O'MELVENY & MYERS LLP
14 BY: VINCENT S. WEISBAND, ESQUIRE
Times Square Tower
15 7 Times Square
New York, NY 10036
16 (212) 326-2228
vweisband@omm.com
17 -- Representing the Janssen Defendants
18 MORGAN LEWIS & BOCKIUS LLP
BY: WENDY WEST FEINSTEIN, ESQUIRE
19 One Oxford Centre
Thirty-Second Floor
20 Pittsburgh, PA 15219-6401
(410) 560-7455
21 wendy.feinstein@morganlewis.com
-- Representing the Teva Defendants
22
23
24

1 APPEARANCES: (Continued)

2 MORGAN LEWIS & BOCKIUS LLP
3 BY: JOHN P. LAVELLE, JR., ESQUIRE
4 1701 Market Street
5 Philadelphia, PA 19103-2921
6 (215) 963-4824
7 john.lavelle@morganlewis.com
8 -- Representing the Defendant
9 Rite-Aid of Maryland, Inc.

10 REED SMITH LLP
11 BY: STEVEN J. BORANIAN, ESQUIRE
12 101 Second Street
13 Suite 1800
14 San Francisco, CA 94105
15 (415) 659-5980
16 sboranian@reedsmith.com
17 -- Representing the Defendant
18 AmerisourceBergen Drug Corporation

19 JONES DAY
20 BY: BRANDY H. RANJAN, ESQUIRE
21 325 John H. McConnell Boulevard
22 Suite 600
23 Columbus, OH 43215-2673
24 (614) 469-3939
25 branjan@jonesday.com
26 -- Representing the Defendant Walmart Inc.,
27 f/k/a Wal-Mart Stores, Inc.

28 ROPES & GRAY LLP
29 BY: RICHARD L. GALLAGHER, ESQUIRE
30 Three Embarcadero Center
31 San Francisco, CA 94111-4006
32 (415) 706-1033
33 richard.gallagher@ropesgray.com
34 and

35 ROPES & GRAY LLP
36 BY: CHRISTINE D'AURIA, ESQUIRE
37 Prudential Tower
38 800 Boylston Street
39 Boston, MA 02199-3600
40 (617) 235-4741
41 christine.dauria@ropesgray.com
42 -- Representing the Defendant
43 Mallinckrodt LLC

1 APPEARANCES: (Continued)
2 THE PIORKOWSKI LAW FIRM, PC
3 BY: JOSEPH D. PIORKOWSKI, JR., ESQUIRE
4 1800 K Street, NW
5 Suite 1000
6 Washington, DC 20006
7 (202) 223-5535
8 jpiorkowski@lawdoc1.com
9 -- Representing the Defendant
10 McKesson Corporation
11 FOX ROTHSCCHILD LLP
12 BY: ZACHARY MARTIN, ESQUIRE
13 (via teleconference)
14 Stone Manor Corporate Center
15 2700 Kelly Road
16 Suite 300
17 Warrington, PA 18976
18 (215) 918-3680
19 zmartin@foxrothschild.com
20 -- Representing the Defendant
21 Prescription Supply, Inc.
22 BARTLIT BECK LLP
23 BY: SHARON DESH, ESQUIRE
24 (via teleconference)
54 West Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494.4445
Sharon.Desh@BartlitBeck.com
-- Representing the Defendant
Walgreens

LOCKE LORD LLP
BY: SARAH LANCASTER, ESQUIRE
(via video stream / realtime stream)
600 Congress Avenue - Suite 2200
Austin, TX 78701
512-305-4756
slancaster@lockelord.com
-- Representing Defendants Henry
Schein, Inc., and Henry Schein
Medical Systems, Inc.

1 ALSO PRESENT:

2 CHRIS RITONA, Videographer
3 Golkow Litigation Services

4 GERARD MAGLASANG, Legal Assistant
5 SEEGER WEISS LLP

6 ALSO PRESENT via video stream/realtime stream:

7 JENNA FORSTER
8 Motley Rice LLC

9 GRETCHEN KEARNEY
10 EMMA KABOLI
11 Baron & Budd P.C.

12 SCOTT SIEGEL
13 CHARLES BACHMANN
14 Seeger Weiss LLP

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16

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 2 I N D E X
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(It is hereby stipulated and agreed

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by and among counsel that sealing,

4

filing and certification are waived; and

5

that all objections, except as to the

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form of the question, will be reserved

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until the time of trial.)

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9

VIDEO OPERATOR: We are now on the

10

record. My name is Chris Ritona. I am

11

a videographer for Golkow Litigation

12

Services.

13

Today's date is April 25th, 2019,

14

and the time is approximately 9:28 a.m.

15

This video deposition is being held

16

at Baron & Budd, 600 New Hampshire

17

Avenue NW, The Watergate, Washington,

18

D.C. in the matter of National

19

Prescription Opiate Litigation MDL

20

Number 2804, Case Number 17-MD-2804, for

21

the United States District Court,

22

Northern District of Ohio, Eastern

23

Division.

24

The deponent today is David A.

1 Kessler, M.D., and all counsel will be
2 noted upon the stenographic record.

3 The court reporter today is Lisa
4 Feissner, and she will now please swear
5 in the witness.

6 DAVID A. KESSLER, M.D.,
7 having been first duly sworn, was examined and
8 testified as follows:

9 EXAMINATION

10 BY MS. FREIWALD:

11 Q. Dr. Kessler, I'm Hope Freiwald. I
12 represent the Purdue defendants in this
13 litigation, but I'm going to be asking
14 questions on behalf of the defendant group as
15 well this morning in addition to questions with
16 regard to Purdue specifically. Okay?

17 A. Good morning.

18 Q. Good morning.

19 Dr. Kessler, do you stand by your
20 prior statements that FDA bears
21 responsibilities for mistakes made regarding
22 prescription opioids?

23 A. I don't believe that's an exact
24 quote. If you can show me my quotes, I'm happy

1 to look at them one by one. That doesn't sound
2 like me, what you just stated.

3 Q. Do you stand by the principle that
4 the FDA bears some responsibility in the opioid
5 crisis?

6 MR. RAFFERTY: Object to the form.

7 A. I think many named parties bear
8 responsibility in the opioid crisis. You've
9 got to be a little more specific. It's a very
10 general statement.

11 If you want to talk about specific
12 conduct of FDA, I'm happy to discuss it, but
13 those kind of broad statements are hard to
14 answer in the abstract.

15 Q. You have stated publicly that the
16 FDA made mistakes with regard to prescription
17 opioids?

18 A. If you have a foundation, Counsel,
19 for that quote, please show it to me, because
20 I'm not sure I said it exactly that way.

21 Q. Do you remember if you conveyed
22 that concept?

23 A. I remember concepts that I
24 conveyed, maybe not every -- maybe not every

1 concept over the last 20 years. But you've got
2 to be specific, Counselor.

3 And just -- I remember -- I'd be
4 happy to tell you what I believe I've said, but
5 if you have specific quotes, I'd be happy to
6 answer them and respond.

7 Q. Sitting here today, do you believe
8 that the FDA bears responsibility with regard
9 to the opioid crisis?

10 A. I think, looking back, as some of
11 my colleagues at FDA said, had FDA known
12 certain things, had they known the extent of
13 the marketing that the companies would do, I
14 think FDA would have and should have done
15 things differently.

16 But I don't think -- certainly when
17 I was at the FDA, had no clue to the extent
18 that the companies -- again, I don't want to
19 talk in general terms, but the kind of
20 marketing pushes that your client and others
21 did.

22 And I think if FDA either -- I
23 think the major mistake FDA made was, in
24 essence, it trusted the manufacturers too much.

1 Q. So you're saying they had no clue
2 about the marketing at any point in the last
3 almost 20 years?

4 A. No, that's not --

5 MR. RAFFERTY: Object to the form.

6 A. That's not what I said. What I
7 said were, obviously, your client pled guilty.
8 FDA knew certain things, as that came out of
9 that criminal investigation, at different
10 points in time.

11 Let's talk -- tell me what year.

12 We can talk about what --

13 Q. You made a broad statement --

14 MR. RAFFERTY: Let the witness
15 finish, please.

16 A. Let me give you an example. Let me
17 give you an example.

18 In 1994, 1993, I confronted an
19 opioid issue when I was at the agency and made
20 certain decisions in changing the label on one
21 product that's at issue here, okay, and tried
22 to narrow the indications after a certain
23 tragedy happened.

24 I had no idea that the company

1 would go ahead and market the compound broadly
2 after that.

3 Q. Okay. So "no clue" is your
4 testimony.

5 A. No, no, no. No --

6 MR. RAFFERTY: Objection to form.

7 Q. Do you stand by your --

8 A. No, no, no. Ma'am, that's not
9 correct. Okay?

10 I don't think the FDA, even to this
11 day, okay, has an understanding of the extent.
12 If you look at the call notes of your client in
13 1996 and 1997 of using these -- I mean, for
14 example, OxyContin --

15 Q. Sir, I'm going to move to strike.
16 I'm asking a different question.

17 A. I want to finish my answer.

18 MR. RAFFERTY: You can move to
19 strike after he finishes his answer.

20 A. Okay. Okay. I don't think FDA, to
21 this day, has a real, full idea of the extent,
22 one, of the marketing.

23 Look at the call notes, as I was
24 saying, in 1996, 1997, of what was going on, of

1 using, for example, OxyContin on junkies in the
2 call notes. I mean, the FDA has any -- has a
3 concept of that.

4 Now, saying that, I can't tell you
5 what every investigator, what everyone at DOJ
6 over the years knows.

7 But I can certainly tell you, when
8 I was at the agency, the extent of the
9 marketing, the sophistication of the marketing,
10 the aggressive nature of the marketing, none
11 of -- that was not understood, certainly by me.

12 Q. Do you stand by your prior
13 statements that DEA bears some responsibility?

14 MR. RAFFERTY: Object to the form.

15 A. Ma'am, if you have a foundation for
16 that question, I'd like to see it, because I'm
17 not sure I've ever said anything like that.

18 But if you have -- but, again,
19 if you have some statements about DEA that I've
20 said -- I usually don't talk in terms of the
21 DEA, but if you have certain statements, happy
22 to look at that.

23 Q. Do you stand by prior statements
24 that doctors bear responsibility?

1 MR. RAFFERTY: Object to the form.

2 A. Again, if you have prior
3 statements, I'd like to see it so I can
4 respond. I'm happy to talk generally, if you'd
5 like, about that, if you want.

6 Q. Sitting here today, you don't
7 recall your prior statements about doctors
8 bearing responsibility?

9 A. Ma'am, I've been interviewed
10 numerous times on this subject. I've written
11 editorials on this subject. I've had numerous
12 conversations on this.

13 I tend to remember my statements
14 pretty vividly, all right, but again, if you
15 have statements, I'd be happy to respond to
16 each and every one of them.

17 Q. Is it your testimony that in
18 preparation for today's deposition, you did not
19 review your statements in public interviews --

20 MR. RAFFERTY: Objection.

21 Q. -- with regard to prescription
22 opioids?

23 MR. RAFFERTY: Object to the form.

24 A. Do you have a basis to ask that

1 question?

2 Q. Sure.

3 A. Okay. I've not testified that I
4 have not done that. You said --

5 Q. I'm asking a question. Is it your
6 testimony that in preparation for today's
7 deposition, you did not review your prior
8 public statements with regard to prescription
9 opioids?

10 MR. RAFFERTY: I think I'm going
11 to -- I'm going to object. And,
12 actually, I think that starts -- what he
13 did to prepare and how he prepared is
14 work product.

15 So you don't have to answer that
16 question.

17 MS. FREIWALD: You're instructing
18 him not to answer what he did in
19 preparation for today?

20 MR. RAFFERTY: I am. The way you
21 phrased that question, yes.

22 Q. With regard to preparing for
23 today's deposition, did you review any prior
24 public statements you have given with regard to

1 prescription opioids?

2 A. Maybe not -- it depends what -- the
3 point where I was preparing.

4 I certainly, over the last period
5 of time, have looked, for example, at certain
6 things I have written. So I have looked at
7 that. I'm not sure they were done in the last
8 week or so, quote, in preparation for this, but
9 I certainly have looked at some of the
10 statements that I have made.

11 Q. In the last week or so, have you
12 looked at any of your press statements?

13 A. I'm not sure I've looked in the
14 last week or so. I'd have -- I just don't have
15 a recollection exactly. I remember looking at
16 an editorial. I think it was a couple of weeks
17 ago. That's what I recall.

18 Q. In preparing your written report,
19 did you review any of the interviews you've
20 previously given with regard to prescription
21 opioids?

22 A. Well, my report was done over a
23 period of time. It was rather lengthy. So I
24 actually did interviews during the

1 preparation -- during the report.

2 So of course the answer would be
3 "yes" because I actually did some interviews
4 while I was -- I mean, you know, during that --
5 during that year-plus period of time.

6 Q. I wouldn't consider that reviewing
7 if you gave an interview.

8 I'm asking if you reviewed any of
9 your prior interviews during the period that
10 you were preparing your report.

11 A. I have -- I remember reading -- the
12 answer is, yes, I remember reading -- because I
13 said one thing that I have written, I asked
14 counsel to try to find.

15 MR. RAFFERTY: Object to the form.

16 You don't have to discuss your --

17 THE WITNESS: Okay.

18 MR. RAFFERTY: -- interactions with
19 counsel, Doctor.

20 Q. I wasn't calling for that in my
21 question.

22 I was just asking whether, in
23 preparing your report, you reviewed any of your
24 prior press interviews.

1 A. Again, leave aside -- in
2 preparing -- in preparing my report, the answer
3 is, yes, I'm sure I did.

4 Q. Are any of them attached or noted
5 as reliance materials?

6 A. I tend not to rely on myself, sort
7 of a loop that one gets into, but --

8 Q. Do you stand by prior statements
9 that other governmental officials bear
10 responsibility with regard to the opioid
11 crisis?

12 MR. RAFFERTY: Object to the form.

13 A. Again, you're putting statements --
14 you're alleging statements that I've made that
15 don't sound like me, and -- I mean, if you want
16 to give me the exact wording, I'd be happy to
17 respond. That just doesn't sound like me.

18 Q. Sitting here today, do you believe
19 that different government agencies bear
20 responsibility with regard to prescription
21 opioids?

22 A. Yes. I mean, I just -- I told you
23 yes. I think that there was too much trust of
24 the industry, too much sense that the -- what

1 FDA thought the indication was would be
2 followed.

3 I don't think anybody -- certainly
4 I didn't anticipate that certain companies
5 would drive a truck through the marketing,
6 broaden the indication, and take any fuzziness
7 in the label and using it as a marketing
8 platform.

9 I think there are statements where,
10 after FDA meetings, your client literally
11 celebrated the things that I know were not the
12 way FDA viewed it but were able to get things
13 past the FDA. So I think that was a mistake.

14 Given how the manufacturers
15 promoted -- again, I want to be careful. I
16 don't want to use terms too broadly. I'm happy
17 to talk about specifics.

18 But certainly with regard to your
19 client, given how your client and certainly
20 others promoted it, I think it was a mistake,
21 how -- and FDA could have been -- they could
22 have been stronger.

23 Q. Other than being -- you used the
24 word "trust." Other than putting too much

1 trust in industry, to use your words, do you
2 believe that other state and governmental
3 agencies bear responsibility?

4 A. You said state and local or state
5 and government --

6 Q. Other governmental agencies. I'll
7 just make it broad.

8 A. I mean, my expertise, Counselor,
9 is really in FDA.

10 Q. Okay.

11 A. So --

12 Q. So I'll modify my question. I'll
13 modify my question.

14 Other than putting trust in
15 industry, do you believe that FDA bears
16 responsibility with regard to prescription
17 opioids?

18 A. There may be --

19 MR. RAFFERTY: Object to form.

20 A. There may be specific, you know,
21 instances where we can talk about where I think
22 FDA could have done better.

23 I said one publicly. FDA approved
24 a super-potent fentanyl compound recently at

1 the request of the Department of Defense.

2 I've had criticisms. I sort of
3 understand why FDA may have done that. I
4 probably would have done something else. I
5 would have done it a different way.

6 But I certainly respect how the
7 agency -- why the agency, because of the
8 Department of Defense, needed to do what it
9 did.

10 Q. Okay. We'll talk about specific
11 examples a little bit later.

12 But with regard to doctors, other
13 than trust, do you believe doctors bear
14 responsibility with regard to prescription
15 opioids?

16 MR. RAFFERTY: Object to the form.

17 A. As I said, I think -- Counselor, I
18 think a lot of people bear, I mean, some
19 responsibility. Some more than others.

20 There's obviously -- there's no
21 doubt in my mind -- I mean, if you look, for
22 example, you know, at the documents in the
23 record, it's quite clear that there were
24 individual physicians who were the top decile

1 who were cash, who were prescribing 80s or even
2 160s at a rate that is hard to fathom.

3 So they certainly -- there were
4 doctors who were arrested. They were -- and
5 again, happy to talk about that. So they
6 certainly bear responsibility for this.

7 I don't think that the medical
8 profession -- I mean, the extent -- I mean, it
9 is almost breath-taking, the amount of
10 influence that the market -- that I think the
11 defendants collectively had on the medical
12 profession.

13 The sophistication to try to
14 influence medicine I think is almost
15 breath-taking. I almost said -- and I thought
16 I had seen a lot.

17 And I think to some extent the
18 medical profession, even to this day, doesn't
19 understand, for example, how KOLs are hired and
20 mapped to the extent that they influence
21 doctors and the return on investment is known
22 to the company by the KOLs and how they get --
23 they can track how they change prescribing.

24 I think to this day, the medical

1 profession does not fully understand the
2 influence the promotional activities, certainly
3 in this instance, had on it.

4 Q. Okay. We'll talk about that later.

5 It's been over two decades since
6 you left the FDA?

7 A. You're dating me. 1997.

8 Q. Okay. When you were at the FDA,
9 you were never part of the advertising and
10 marketing division, correct?

11 A. That would probably -- that would
12 probably be incorrect, as stated just
13 generally.

14 Obviously I was in charge of the
15 agency. I think if you asked, for example, Ann
16 Witt or Lucy Rose, they'd probably say, hey, I
17 was part of it.

18 Q. You were never within the division?

19 A. Can I finish my answer, please?

20 I ran the division. I revitalized
21 the division. Those directors and people in
22 DDMAC, is what it was called, reported to me
23 directly. We met. I think I would be -- fair
24 to say that I was involved.

1 You know, obviously I was doing
2 other things, so I couldn't do anything, but I
3 sort of tried to revitalize that division
4 within CDER.

5 Q. Sir, it's a simple question.

6 I understand you were Commissioner.
7 And as Commissioner, the buck stopped with you,
8 correct?

9 A. That's fair.

10 Q. And you had oversight over all the
11 divisions?

12 A. You're missing my point.

13 Q. No. I want to be clear what my
14 question is.

15 A. Okay.

16 Q. Were you ever within the division
17 that was once called DDMAC and is now called
18 OPDP?

19 MR. RAFFERTY: Object to the form.

20 A. And I think I --

21 MR. RAFFERTY: Asked and answered.

22 A. I think I answered that. I think
23 if you ask Lucy Rose or Ann Witt, who ran that,
24 they would say that I was pretty tied to that

1 division for a period of time. Certainly not
2 on everything.

3 Obviously if you looked at my
4 organizational chart, it didn't say DDMAC,
5 right. But I did meet with them, and I did --
6 I put them in as leaders, and they, in
7 essence -- we worked together was probably a
8 best way to characterize it.

9 Q. There's no org chart that would
10 ever show you as part of DDMAC?

11 A. It would show me -- as reporting to
12 me.

13 Q. Okay. And you started doing
14 litigation work after you left FDA?

15 A. I use the term "litigation work" --
16 actually, is that correct?

17 I was the expert witness in the
18 Department of -- I'm just trying to think --
19 for the Department of Justice initially. So I
20 testified there. I have testified, I think is
21 the right way to say it.

22 Q. How much money over the last
23 20-some years have you made testifying as a
24 witness for plaintiffs' lawyers?

1 A. Well, again, for plaintiffs'
2 lawyers, I don't -- I'm not sure. I testified
3 for certain clients, but -- on certain -- a
4 majority of that is on the plaintiffs' side, a
5 substantial majority. I've made millions of
6 dollars.

7 Q. 10, 20, 30?

8 A. I have no idea, but I would not
9 think that it would be that high. But I have
10 no idea. I have no idea.

11 Q. You have no idea how much money
12 you've made over the last ten years?

13 MR. RAFFERTY: Object to the form.

14 A. No, I certainly don't have any idea
15 of that.

16 Q. I want to show you --

17 MS. FREIWALD: Can I get a --

18 (Exhibit Kessler-1 marked for
19 identification and attached to the
20 transcript.)

21 BY MS. FREIWALD:

22 Q. Exhibit 1 is your report. It
23 looked to me like you have a copy of your
24 report with you. Or do you not?

1 A. Yes, I have a spiral copy.

2 Q. Okay. You have some -- are those
3 just tabs that you have in there, or is there
4 something else that you have inside your
5 report?

6 A. I have a couple of other documents
7 in the back, but this is my report, and these
8 are tabs that are just telling me where certain
9 things are.

10 Q. Okay. So --

11 A. I think it --

12 Q. -- I have an unbound version of the
13 report, because I thought it would be easier
14 for the court reporter. We can also give you a
15 bound version if -- it's marked as Exhibit 1 --
16 unless you want to use your version.

17 The version that I have has all of
18 the exhibits and the CV, with the exception of
19 the one that was produced natively.

20 MS. FREIWALD: And can I get
21 the native -- there's a native exhibit
22 also.

23 MR. RAFFERTY: It's in the back of
24 that one.

1 Q. Okay. So it's in the back of that
2 as well.

3 Do you have your report and your CV
4 and your exhibits, or do you need a copy from
5 me?

6 A. No, I have it. Thank you,
7 Counselor.

8 MS. FREIWALD: Do you need a copy,
9 Troy?

10 MR. RAFFERTY: That's all right.
11 I've got it.

12 Q. Now, while you were at FDA, you
13 never formed an opinion, did you, that opioids
14 should not be available and used as indicated?

15 A. I think the record reflects my view
16 certainly on specific compounds. If you look
17 at the record and statements to the Hill that
18 were made by the agency -- I'm happy to tell
19 you what my statements were on those opioids.

20 Q. You never took the position
21 generally that opioids should not be available
22 for the treatment of moderate to severe pain?

23 A. I took a very specific position
24 with regard to Duragesic that -- if you look at

1 a letter to -- for example, to Connie Mack, who
2 is senator of Florida, on Duragesic, I took a
3 very specific position that it was appropriate
4 to use opioids in cancer patients and that
5 there may be, on a very restricted basis,
6 non-cancer patients who might benefit.

7 I can give you the --

8 Q. That's okay.

9 A. -- exact terminology if you'd like.

10 Q. That's okay. That wasn't my
11 question.

12 My question was, you never took a
13 position generally that opioids should not be
14 approved and used for moderate to severe pain?

15 MR. RAFFERTY: Object to the form.

16 A. Yeah, so here's the actual
17 statement to the position of your statement.

18 Q. I want to ask my question.

19 A. You can ask your question, and I'm
20 answering it, ma'am.

21 What I've said -- what was said for
22 me -- I mean, what I said, and it was conveyed
23 to Congress, is: Consideration was given to
24 limiting the approved indication for the

1 product to the treatment of pain of malignancy.
2 But it was known that there was a small
3 fraction of chronic pain patients with pain of
4 non-malignant origin who can also potentially
5 benefit from the product.

6 So what I did recognize, right, was
7 that opioids -- I mean, certainly in this
8 case -- should be used with regard to cancer
9 pain, and there -- and that there would be a
10 small fraction of patients who might benefit.
11 That was --

12 Q. Sir, my question was generally --

13 MR. RAFFERTY: Let him finish his
14 answer.

15 MS. FREIWALD: He's not answering
16 my question.

17 MR. RAFFERTY: He is exactly
18 answering your question, Ms. Freiwald --

19 MS. FREIWALD: My question was
20 whether --

21 MR. RAFFERTY: -- and he can -- you
22 cannot stop him. Let him finish. If
23 you want to move to strike, move to
24 strike. But that is a direct -- direct

1 answer to your question.

2 MS. FREIWALD: No. My question
3 wasn't about Duragesic; it was
4 generally.

5 MR. RAFFERTY: Yeah.

6 Q. Generally speaking, did you ever
7 take the position that opioids as a class
8 should not be available for use for moderate to
9 severe pain --

10 MR. RAFFERTY: Object to the form.

11 A. So --

12 Q. -- while at FDA?

13 A. I didn't make a statement in
14 exactly those terms.

15 The two opioids that I have -- that
16 I dealt and did make statements on -- one, I
17 just told you what was the position.

18 The other one was even in a more
19 restrictive -- I thought it should be
20 available. It was the predecessor to Actiq.
21 It was Oralet. And I insisted personally that
22 the agency put very strict controls around that
23 product and, in essence, restricted
24 distribution to certain pharmacists. So I

1 restricted that product.

2 Those are the products that I dealt
3 with.

4 Q. You never took any position with
5 regard to MS Contin?

6 A. I don't believe I was involved in
7 MS Contin while I was at the agency.

8 Q. MS Contin was an approved opioid
9 while you were at the agency, correct?

10 A. It was approved prior to my being
11 at the agency, and --

12 Q. And it was approved while you were
13 at the agency. I don't mean that the --

14 A. No.

15 Q. -- approval happened while you were
16 at the agency. I mean that it was an approved
17 product that was available for prescription
18 while you were the Commissioner of the agency.

19 A. That's correct. And I wasn't --
20 just so the record is clear, I was not
21 involved -- I have no recollection of any issue
22 that was brought to me with regard to
23 MS Contin.

24 Q. And MS Contin was approved and

1 indicated for moderate to severe pain for more
2 than a few days at the time?

3 A. That was what the label said. It
4 was generally understood that it would be used
5 for cancer pain.

6 Q. That's not what the indication was.
7 The indication was for moderate to severe pain
8 for more than a few days?

9 A. I think if you look at the record
10 and you look at what the intended population
11 was, I think the record would show that the
12 intended population was for cancer patients.

13 Q. I asked you what the indication
14 was.

15 A. You can show me the label, and we
16 can read it, but -- my recollection is, you're
17 pretty much right. But again, the indication
18 subsumes an intended population. And if you go
19 back and look at the record, I think the
20 intended population of MS Contin was for cancer
21 patients.

22 Q. Well, the FDA knows how to write an
23 indication for the population -- for the use
24 that it intends to treat, correct?

1 A. Not -- not if you're -- not if
2 you're going to drive a truck through it. If
3 you look at -- if you looked, in fact, at
4 specifically the comments by your research
5 center --

6 Q. I'm asking about MS Contin.

7 MR. RAFFERTY: Object to the form.

8 Q. I'm still on MS Contin.

9 A. I'm answering -- I'm answering your
10 question, ma'am.

11 Q. I'm still on MS Contin, sir.

12 A. That's fine. If I can just finish
13 my question, please. Let me just please --

14 I don't think the agency fully
15 understood -- I think there was less of an
16 issue with MS Contin, but I think that if you
17 look at the record, the celebrations after the
18 label was written, certainly on MS Contin's
19 successor, on OxyContin, was that it was clear
20 that your company thought that all the
21 promotion -- and you were instructed that all
22 the promotional material would disappear from
23 the labeling, but you celebrated after the
24 label, that, the label contained all the major

1 elements of our long-range marketing plan.

2 Q. Sir, I promise you we will talk
3 about MS Contin -- I mean, about OxyContin
4 later. I promise.

5 A. That's fine, but -- but --

6 Q. Right now I'm asking you about
7 MS Contin, and I'm also asking you about the
8 FDA's ability to create a label.

9 A. That --

10 Q. The --

11 A. And I've -- I've answered --

12 Q. You weren't involved in MS Contin,
13 right?

14 A. But -- but let me --

15 Q. Sir, no.

16 (Reporter interruption.)

17 Q. So you gave me your full answer, so
18 now I want to ask you a different question.

19 A. No, ma'am. I didn't give you my
20 full answer.

21 You asked me about FDA's ability to
22 write a label, okay? And FDA's ability to
23 write a label depends on a good-faith
24 understanding of what the manufacturer intends.

1 Q. Okay.

2 A. And in this case, what FDA clearly
3 was saying to your client was that OxyContin
4 was supposed to be limited, right, and your
5 client did not listen to that. So FDA did not
6 write a label, in my opinion, that anticipated
7 how your client would market this drug.

8 And I think the record reflects,
9 when you look at the documents, that -- that
10 the label -- the documents show you walked out
11 of, for example, a 2001 meeting where FDA --

12 Q. Sir, I have seven hours with you,
13 and I asked you a question about MS Contin --

14 A. But you're asking me about FDA
15 knowing how to write a label. FDA worked very
16 hard with your client to write a label, right,
17 and in 2001 restricted OxyContin. John Jenkins
18 tried his best.

19 They called your client the bad
20 actor. Your client went out after that meeting
21 and said, we can promote this broadly. It was
22 completely antithetical to what FDA said and
23 was asking your company to do.

24 So what I'm saying is that FDA

1 can't write a label if you're going to drive a
2 truck through it. There is no -- the English
3 language is not that precise, right, to foresee
4 and was not able to see how this marketing --
5 this marketing avalanche would take the words
6 in the label.

7 Q. Sir, I have -- my question is, can
8 the FDA write a label, if it wants, that says,
9 "Indicated for cancer pain"?

10 A. The FDA could write such a label.
11 I could have written that label and changed it
12 in 1994. I -- I --

13 Because -- and I think this is the
14 issue. Because the FDA -- I mean, we -- wants
15 to make sure that it doesn't foreclose, in
16 certain small instances, people having access
17 when they desperately need access, right. I
18 said, beyond cancer pain, there's a small
19 fraction, all right?

20 I mean, it becomes -- there has to
21 be an understanding, right, between a company
22 and the FDA. When I say that it can be used
23 for cancer and it's useful for a small
24 fraction, it shouldn't be used broadly for back

1 pain and osteoarthritis.

2 I could not have written a -- I
3 mean, I probably could have, right, tightened
4 up the label, but I was -- wanted to make sure,
5 in my instance, that it was available for a
6 small fraction of non-cancer.

7 That -- in my wildest dreams, I
8 would never have believed that a company would
9 go out and market it broadly for chronic back
10 pain and osteoarthritis.

11 Q. Sir, we're just talking about
12 MS Contin now, okay? You had left the agency
13 after '97. So let's just stick with MS Contin.

14 You -- the FDA could write a label
15 that said, for cancer pain, or for other
16 specific types of pain, or limit the indication
17 as to duration or dose, or in any other way.
18 The FDA can do that?

19 MR. RAFFERTY: Object to the form.

20 Q. I'm not getting to yet whether the
21 FDA should have in the first instance.

22 A. So the --

23 Q. They can do that, right?

24 A. Well, let's discuss this.

1 MR. RAFFERTY: Make sure we let
2 everybody finish.

3 A. When you say "can do that," at what
4 point in time are you asking about?

5 Q. I'm not asking -- irrespective of
6 responsibility or who knew what, the FDA has
7 the ability to write a label that is that
8 specific, if they want it to be?

9 A. So let's be clear. FDA has -- FDA
10 can at this point in time, before 2007,
11 right -- FDA could hold up a drug, but the
12 label used was -- everyone, I think, would
13 tell -- agree that labeling was a
14 back-and-forth.

15 It is not true that once a drug is
16 on the market, that FDA can just, prior to
17 2007, order a change in the label. If you look
18 at the labels, most of them are copyrighted.
19 They are -- as my colleague Sandy Kweder said
20 at the agency, it's the company that owns the
21 label.

22 Q. Is it your testimony that prior to
23 2007, the FDA could not order a company to
24 change the labeling?

1 A. Unilaterally, no. That is correct.
2 That's why the 2007 Act was put in where FDA
3 had that authority.

4 Obviously, FDA could go to court.
5 It could say it's misbranded. But it could not
6 say, just go change the label. It was a
7 negotiation.

8 Q. So we'll talk about that authority
9 a little bit later.

10 To be clear, in none of the
11 following years did you come forward and
12 publicly critique or recommend any changes in
13 the label with regard to any prescription
14 opioid after reports of Maine in 2000, you
15 didn't come forward and say, we should look at
16 this label differently, did you?

17 A. I was -- I didn't -- Maine, I --
18 I'm not sure I -- when I knew anything about,
19 quote, Maine.

20 Q. Okay. After the --

21 A. You're talking about --

22 Q. -- Senate Finance hearing in 2001?

23 A. I was not making -- I -- I was not
24 studying -- I was not at the agency. My

1 comments at the agency were -- I mean, are on
2 record while I was at the agency. I read you
3 some of them, and I --

4 Q. At the time of the black box
5 warning in 2001?

6 A. I was not necessarily following
7 this at all.

8 Q. Okay. Following warning letters in
9 2002 and 2003?

10 A. I wasn't at the agency, ma'am.

11 Q. Okay. So you weren't -- you
12 weren't involved in any of this?

13 A. I wasn't at the agency, no.

14 Q. Okay. So in real time, you weren't
15 looking at the issue in 2007, after there was a
16 public plea agreement?

17 MR. RAFFERTY: Object to the form.

18 Q. You weren't involved?

19 A. No, I was not involved.

20 Q. Okay. And in 2008, at the time of
21 Senator Blumenthal's citizen's petition asking
22 for labeling changes, you weren't involved?

23 A. Not at all.

24 Q. You didn't have any real-time

1 knowledge of these issues?

2 MR. RAFFERTY: Object to the form.

3 A. I may have read the newspaper, I
4 may have watched TV, but I was a public
5 citizen -- public citizen watching.

6 Q. Okay. And in 2010, at the time of
7 ADF approval, the abuse-deterrent formulation
8 approval, ADF, you -- you weren't -- you
9 weren't engaged in any of these issues
10 real-time?

11 MR. RAFFERTY: Object to form.

12 A. So by that time, there were -- I'm
13 just trying to think.

14 I'm a senior advisor at
15 TPG Capital. I remember my colleague,
16 Sandy Robertson, one of the -- you know, in San
17 Francisco, once had somebody -- had some
18 questions about an ADF product. People would
19 ask me questions.

20 And I began to get phone calls.
21 I'm trying to think when -- I don't -- I don't
22 have a specific recollection, but my guess,
23 around that time, I'm getting phone calls from
24 press, right?

1 Q. Okay.

2 A. I mean, or occasionally here or
3 there, or somebody's asking me an ADF question.
4 I mean, at that point in time it's becoming
5 public health, and so I'm -- you know, I'm
6 getting asked for what I think about certain
7 things.

8 Q. Were you getting any information
9 from how -- that wasn't public about how the
10 agency was viewing these issues?

11 A. I'm trying to think. There
12 would -- there would be an -- I don't think it
13 would be fair to say I was getting things that
14 were not public.

15 I would get a phone call. I
16 remember Peggy Hamburg would call me every once
17 in a while and ask me advice on certain
18 questions. I didn't reach in, but she would
19 call me, and opioids may have come up. I just
20 don't have a -- I'm sure they did. More
21 likely. But she would call me for advice.

22 Q. Sitting here today, can you recall
23 any situation where, as a non-employee of FDA,
24 you gave advice to FDA with regard to

1 abuse-deterrent formulations?

2 A. I don't have a recollection. I
3 don't have a recollection of ever doing that.

4 Q. And you were talking to Dr. Hamburg
5 in the 2010-ish time period?

6 A. No, I don't -- I think Peggy was
7 Commissioner at that time -- again, I don't
8 want to -- this would be an occasional, every
9 six months or so, she wanted advice --

10 Q. Fair to say you were not involved
11 in this time period in what the FDA was
12 thinking or how they were processing
13 information internally?

14 A. Other than what -- other than what
15 they were saying publicly.

16 Q. Okay. And would the same thing be
17 true in the 2010-'11 or so time period with
18 regard to the joint REMS?

19 A. I was not involved.

20 Q. Okay. So you weren't --

21 A. I was not involved from an FDA
22 perspective. I'm just a public citizen at this
23 point.

24 Q. Okay. So you weren't getting -- in

1 all this time period, you weren't getting
2 information real-time about how the FDA was
3 processing any of this information, what they
4 were thinking about it, what they knew or
5 didn't know?

6 A. No, unless it came up in a
7 conversation. But sitting here today, I just
8 don't -- I just -- it doesn't pop into my head.

9 Q. Okay. So from 1997 -- strike that.
10 And I assume the answer would be
11 the same in 2013, at the time of the PROP
12 citizens' petition, you weren't involved -- you
13 didn't have any access to how the FDA was
14 thinking about these issues other than what any
15 public citizen would have?

16 A. That's correct.

17 Q. Okay. And since 2013, you haven't
18 had any access to how the FDA has been thinking
19 about the issues of opioid prescribing, abuse,
20 misuse, other than what you can glean as a
21 public citizen?

22 A. That probably would not be
23 accurate.

24 Q. If I exclude what you've looked at

1 in the context of litigation, what aspect of
2 that would not be accurate?

3 A. Well, I've had conversations for
4 other reasons with people at the agency.

5 Q. And what would that be?

6 A. So for example -- I have to refresh
7 my memory exactly. So I would have -- when I
8 started getting called by a 60 Minutes producer
9 who was doing a piece, and it was a piece that
10 was focusing part on FDA, and they wanted me to
11 go on camera, and I ended up talking with a
12 certain FDA official at the time.

13 Q. Who did you speak to in advance of
14 the 60 Minutes piece at FDA?

15 A. I may have spoken to a number of
16 people, but I certainly remember talking --
17 well, I certainly remember talking to
18 Janet Woodcock a number of times. I know the
19 Commissioner called me to get my views around
20 that time.

21 Q. What views did you give the
22 Commissioner around that time?

23 A. What views --

24 Q. Views. You just said the

1 Commissioner called you to get your views. So
2 my question is, what views?

3 A. Well, he called me to -- he asked
4 me for my views. We talked -- it was a number
5 of subjects. We talked about the Department of
6 Defense and their interest in having access to
7 the super-fentanyl on the battlefield.

8 We also talked about really what
9 would need to be done in the -- with regard to
10 the opioid crisis. And I said I thought there
11 needed to be the equivalent of the truth
12 campaign that we did in tobacco with regard to
13 opioids, I think I told the Commissioner. And
14 we talked a little bit our generations as
15 medical students and how I was taught -- I
16 mean, I used opioids very sparingly.

17 Q. So --

18 A. Can I finish my answer? Just give
19 me one more second. I apologize.

20 And he said, you know, he was a
21 medical student several decades after me, and
22 he was taught just the opposite. And it was
23 really, how can we get to the point of
24 unteaching the medical profession what his

1 generation had been taught. That was the
2 conversation.

3 And then he talked a little
4 about -- we talked about how -- I remember how
5 things in the label -- I remember exactly --
6 even to this day, you know, the fact is that
7 there are not long-term studies, and the label
8 doesn't reflect that. And even to this day,
9 that label could still be improved.

10 Q. So just a couple of things. What
11 generation are you claiming was taught
12 differently from you?

13 A. Scott talked -- Scott character --
14 I mean, I don't want -- he can speak for
15 himself. I don't want to speak for him
16 publicly. But you're asking me a question;
17 I'll answer it.

18 Scott viewed himself as when he
19 went to medical school -- but I assume it was a
20 good 15 years after I did, if not 20 years
21 afterwards. And we just talked -- we talked
22 about how we were taught very different things.

23 Q. So you shared your view with
24 Dr. Gottlieb at that time that opioids were

1 prescribed too broadly?

2 MR. RAFFERTY: Object to the form.

3 A. I don't think -- you're
4 mischaracterizing --

5 Q. So I'll ask it -- what -- the --
6 the premise for my question was your statement
7 that you were asked your views in a
8 conversation with Dr. Gottlieb with regard to
9 opioids. So what I want to know is not so much
10 what he told you but what you said to him.

11 A. I think I -- I think I -- I think I
12 answered that, Counselor. I told him I thought
13 there needed to be a very significant public
14 campaign of the type that we did post-tobacco.
15 And we talked a little about that. And then we
16 sort of reminisced about how -- what I was
17 taught and what he was taught, and it was clear
18 that he was saying he was taught very
19 differently than I was taught.

20 Q. So is it your testimony that at
21 that time, the Commissioner of the FDA had a
22 view that opioids were overprescribed?

23 A. Oh, I think he clearly -- in his
24 public statements, I think if we go through his

1 public statements, he thinks that the access
2 was -- clearly needed to be restricted.

3 Q. So that was known at that time?

4 MR. RAFFERTY: Objection. Let him
5 finish his answer please, Hope.

6 A. Well, we're talking relatively
7 recently --

8 Q. Okay.

9 A. -- that he thinks that it is a
10 question -- I certainly had a sense that he
11 believed that he was taught to prescribe
12 opioids too broadly.

13 Q. Okay. Other than at the time of
14 the 60 Minutes interview, did you have any
15 insight with regard to FDA's thinking about
16 opioids between 1997 and today, other than what
17 a public citizen would have?

18 A. I may have had conversations. I'm
19 sure I had conversations over the years. This
20 was front burner at meetings, at dinners with
21 individuals.

22 Q. To the extent the FDA was public on
23 a whole bunch of fronts, but you weren't
24 involved in any specific decision with regard

1 to any specific product, correct?

2 A. Absolutely not. I mean, I -- and I
3 don't sit here speaking for FDA today. We
4 should be very clear about that.

5 Q. Okay. And you don't -- you're not
6 in a position to say what any particular
7 reviewer thought or didn't think in its -- at
8 the time that they were engaging with any
9 company on any issue?

10 MR. RAFFERTY: Object to the form.

11 A. I think I probably am --

12 Q. And --

13 A. -- a little able to do that.

14 Q. You weren't there, right?

15 A. No, but I have had -- no, but I
16 believe I am able to tell you what certain
17 individuals were thinking at the time because
18 I've had conversations and have asked those
19 questions.

20 Q. Which individuals are those?

21 A. I've had conversations with
22 Curtis Wright.

23 Q. And who else?

24 A. He's probably the only -- I don't

1 want to say -- he's the one I recall -- he's
2 the one I could tell you what -- because I've
3 asked him specifically what he was -- again, I
4 don't want to use the words "subjectively
5 thinking," but I can tell you what he told me
6 that his reasons for doing certain things were
7 and how he looked at certain things.

8 Q. When did you speak with Dr. Wright?

9 A. I've spoken to Dr. Wright for -- a
10 number of times. For example, when I was doing
11 the editorials, I wanted to understand certain
12 things. At the time when I was doing that
13 first -- an editorial in The New York Times --
14 that op-ed, sorry, it's not an editorial --
15 that op-ed piece, I had a number of
16 conversations with Curtis.

17 And I think even before 60 Minutes,
18 when 60 Minutes was asking me certain
19 questions, I wanted to make sure that I was
20 going to be accurate and, again, privately
21 spoke to Dr. Wright.

22 Q. Is that documented anywhere?

23 A. I may have certain documentation.

24 Q. What do you think you have?

1 A. I'd have to go back and see what I
2 have.

3 Q. Did you keep notes of those kinds
4 of conversations?

5 A. It's possible. It certainly is
6 possible that there may be, in preparation for
7 that. I just don't recall.

8 Q. Are you saying there was more than
9 one conversation?

10 A. Oh, yes. I've talked to
11 Curtis Wright several times.

12 Q. And did you speak to Curtis Wright
13 or attempt to speak to Curtis Wright in
14 connection with this report?

15 A. No. I spoke to Curtis Wright --
16 nothing to do with this report. I was being
17 asked certain questions specifically by news
18 organizations and by 60 Minutes, and I wanted
19 to be able to answer for the -- I mean, in
20 essence, I was being put up for the agency.
21 That was the way the producer saw it. Because
22 the agency didn't want to go on camera.

23 Q. Did you speak to Dr. Wright with
24 regard to any of the documents that you

1 attached to your report?

2 A. Absolutely not.

3 (Reporter interruption.)

4 Q. Did you speak to Dr. Wright with
5 regard to any specific approval decision with
6 regard to OxyContin?

7 A. I did.

8 Q. And what is -- what is it that you
9 believe that conversation was?

10 A. So the conversation I had with
11 Curtis, the sum and substance of the 60 Minutes
12 piece was that there was no adequate and
13 well-controlled trials past 14 days. I think
14 there was some open trials.

15 But 60 Minutes's premise was that
16 there was nothing more -- there was no clinical
17 studies -- adequate and well-controlled
18 clinical studies beyond 14 days. That was
19 their premise. They sent me documents to that
20 effect, I believe, I mean, or showed me
21 something, or made certain representations.

22 And I wanted to understand from
23 Curtis, because I was going to have to respond
24 to that, how the agency would -- why would the

1 agency approve something, in Curtis' instances,
2 for more than a few days, but then an extended
3 period of time -- oh, and I also spoke to
4 John Jenkins with regard to this question. And
5 John Jenkins did it for more than a few days --
6 more than a few days, and then it was for an
7 extended period of time.

8 And what I -- what I was being
9 asked -- what I was going to be asked was, how
10 could the agency approve this drug when there
11 weren't adequate and well-controlled clinical
12 studies for more than 14 days?

13 So I posed that question to Curtis
14 directly.

15 Q. And his answer, as you recall it?

16 A. So again, he can speak for himself,
17 but his answer was, David, you have to
18 understand, when this application came in, what
19 this was about was -- this was a new delivery
20 form. So in the 1980s and 1990s, there was new
21 extended release, and this was solely a -- this
22 was a change in delivery form.

23 So my job, saying -- Curtis saying,
24 my job was, I looked at this -- at OxyContin

1 q12 and I wanted to know whether it performed
2 and whether it was as safe and effective as the
3 q4 to 6. So it was, in essence -- I'm going to
4 use a term that's not exactly accurate --
5 bioequivalence, right, did it perform the same?

6 So all I tried to do -- I didn't --
7 I mean, if -- that's what I was trying to do,
8 so I just looked at it to see whether it
9 performed the same. And that's why I didn't
10 require anything other -- in fact, if anything,
11 I think he would say he required more safety
12 studies than would be required for a
13 bioequivalence study. He didn't know, I mean,
14 certainly that all of medicine would change on
15 the back of that approval.

16 Q. And that was consistent with how
17 FDA approached comparable changes in delivery
18 methods at that time?

19 MR. RAFFERTY: Object to form.

20 A. I think that would be a fair
21 statement, Counselor.

22 Q. Okay. So other than the
23 conversations you've described, is there any
24 conversation that you've had with any reviewer

1 at the FDA with regard to how they were looking
2 at the approval or any regulatory change with
3 regard to any of the products that you are
4 commenting on on this litigation?

5 A. I had a conversation with
6 John Jenkins.

7 Q. And what was that -- first of all,
8 when was that conversation?

9 A. Also around the time of 60 Minutes.

10 Q. Okay. And what was that
11 conversation?

12 A. So 60 Minutes -- 60 Minutes was
13 very focused on why the label was changed in
14 2001 from more than a few days to an extended
15 period of time. They were very focused on that
16 label change. And they had sent me minutes of
17 a meeting -- several minutes or told me about
18 certain meeting minutes with Cynthia McCormick
19 and with John Jenkins.

20 And 60 Minutes' position was that
21 was a mistake, that the agency should have
22 tightened up that label. And in fact, it
23 was their view, 60 Minutes, it wasn't a problem
24 with the '96 label; it was a problem with the

1 2001 label. That was the thing focusing on by
2 60 Minutes.

3 So -- and I read the -- or I read
4 the minutes of the meeting with John Jenkins.
5 And I wanted to understand what Jenkins was
6 thinking and what he was saying to your client
7 in 2001.

8 And this is where there was, I
9 think, a very big disconnect. Jenkins said --
10 I mean, if you look at those minutes and -- I
11 think -- hold on a second. I may even have --
12 let me just see -- no, no.

13 Jenkins -- I'm interested if anyone
14 has a copy of those 2001 -- I think it was
15 April meeting minutes.

16 Jenkins was very concerned
17 that there -- I mean, the agency was very
18 concerned at that meeting that there was
19 increasing overuse -- overpromotion,
20 inappropriate selling of OxyContin. I mean, it
21 was very direct. That was the bad actor
22 statement.

23 But what Jenkins also says in that
24 or in a meeting several months after -- and I'm

1 conflating my dates -- was that he wanted to
2 restrict the label to -- and I may not get this
3 exactly right -- but continuous, around -- to
4 when pain was continuous, around the clock, and
5 was unremittent. So it would not be arthritis,
6 all right? I mean, he was trying to narrow the
7 indications, right, where it was -- and he
8 said, David, I was very clear that I was trying
9 to make sure this drug was not to be used for
10 routine osteoarthritis, routine chronic back
11 pain; that basically it would be used third
12 line plus.

13 He didn't quite use those terms,
14 but he was narrowing, he was giving the
15 indications when pain never went away, when it
16 was severe enough that no alternative. And so
17 that's what Jenkins said to me.

18 And what the sort of disconnect
19 was, was, you see the meeting notes by Purdue
20 after that which said that, we walked out of
21 the meeting and we got a completely broad
22 indication to market for almost anything.

23 It was a complete disconnect.

24 Q. So the extended-period-of-time

1 language was intended, as you understood from
2 Jenkins, to be a narrowing of the label,
3 correct?

4 A. That was what he vigorously said to
5 me.

6 Q. And you have not spoken to anybody
7 at Purdue to know how they viewed that change?

8 A. So I --

9 MR. RAFFERTY: Object to the form.

10 Q. I'm not asking you about what
11 you've read; I just want to know whether you've
12 spoken to anybody at Purdue.

13 A. No. But I think the record is very
14 clear and I could find it.

15 Q. We'll look at that memo later.

16 A. You --

17 Q. I know what you're --

18 A. You know what I'm talking about.

19 Q. I know exactly what you're talking
20 about, and we can look at it later.

21 A. Fine. So no, I --

22 Q. But I just want to be clear, you
23 have not spoken to anybody at Purdue?

24 A. No. I would assume that would be

1 inappropriate.

2 MR. RAFFERTY: Object to the form.

3 Q. And you're -- so you're reading
4 from a document about a meeting that you were
5 not at, correct?

6 A. That's correct.

7 Q. Okay. And the person that you've
8 spoken to said that moving the label language
9 from more than a few days to an extended period
10 of time was the agency's effort -- one of the
11 agency's efforts at that time to narrow the
12 indication?

13 A. Yes, because it did not -- Jenkins
14 viewed it as, he didn't want it to be used for
15 the things that it was going -- that it was
16 being -- chronic back pain and osteoarthritis.
17 That was his goal.

18 Q. And he didn't want it to be used
19 for people who just had short-term pain,
20 correct?

21 MR. RAFFERTY: Object to the form.

22 A. He certainly didn't want -- the
23 extended release was not indicated for acute
24 pain at the time, that's correct.

1 Q. Okay. And he was very clear about
2 that. He did not want it for acute pain.

3 A. You know, what we should do -- so
4 my memory may be -- if you can give me -- you
5 know exactly the meeting minutes that I'm
6 talking about where -- we should probably have
7 those in front of us to be exact, exactly what
8 he's saying. But I'm telling you my -- I mean,
9 what he said to me.

10 Q. Okay. And we'll talk about that
11 later when we get into more of the
12 Purdue-specific stuff.

13 A. Sure.

14 Q. But that was only one aspect of
15 what the FDA did at that time to tighten the
16 label and make the warnings more prominent,
17 correct?

18 A. Yeah. I think that would be fair,
19 because at FDA, Tom Abrams said, for example,
20 at that meeting, you know, you've got to
21 convince the world -- you've got to change this
22 perception that you're different than morphine.
23 You're not different than morphine.

24 And I think that was at least the

1 beginning of, quote, "risk maps," as we know
2 that --

3 Q. Okay.

4 A. -- even though that term may not
5 have been used.

6 Q. And there was an understanding at
7 that time by the FDA that the product was being
8 marketed for moderate to severe pain,
9 irrespective of the disease state.

10 MR. RAFFERTY: Object to the form.

11 A. I can't -- we'd have to go back and
12 look at that -- sorry. We'd have to go back
13 and look at that letter so I can be exactly
14 sure.

15 Q. Well, you --

16 A. Whatever it says in those meeting
17 minutes I think reflects what FDA's
18 understanding.

19 Q. Well, you've offered broad opinions
20 about what FDA understood about marketing or
21 not marketing.

22 I want to know, sitting here today,
23 do you remember what FDA understood about the
24 patient populations to whom OxyContin was being

1 marketed in 2001?

2 MR. RAFFERTY: Object to the form.

3 A. So in talking, again, to -- Jenkins
4 was there in 2001. And I certainly recall that
5 those meeting minutes talking about --
6 Cynthia McCormick saying, we don't want this
7 being used for any type of lumbago or -- I
8 mean, I think was her quote.

9 And I think she -- I take it that
10 they had some sense that it was being marketed
11 for that. But I can't quite tell you -- well,
12 that's not true. I apologize. Let me just
13 check one thing, if I may.

14 So we have to look exactly at
15 the --

16 Q. We'll do that all --

17 A. Hold on a second. But what we can
18 do very well is probably make sense to pull --
19 and I have them right behind me -- the DDMAC
20 letters will tell you what FDA was on the
21 record saying. And I think your client had
22 four -- we can go -- warning letters and we
23 can -- that probably reflects at least some
24 extent what the company knew.

1 Q. You think Purdue had four warning
2 letters?

3 A. DDMAC letters? I can check.

4 Q. Okay. Well, we --

5 A. Let me -- I can check --

6 (Simultaneous speaking.)

7 Q. No, we'll do that later.

8 A. I have the book behind me. I have
9 the letters behind me.

10 Q. Okay. I want to talk more
11 generically now. We'll certainly get to that.

12 But sitting here generally, you
13 would agree, wouldn't you, that at least in
14 2001, the FDA knew that extended release
15 OxyContin was being promoted beyond just cancer
16 patients?

17 MR. RAFFERTY: Object to the form.

18 A. I'd want to review the DDMAC
19 letters before I answered that question
20 precisely.

21 Q. Okay. You don't know that just
22 from all the work you've done in this case?

23 MR. RAFFERTY: Object to the form.

24 A. You're asking me -- I want to be

1 precise here exactly what they knew was
2 promoted. I don't have an internal FDA record,
3 I've not seen, of what they knew exactly when.
4 I don't know, for example, I mean -- I know
5 2007 refers to that time period in -- the
6 criminal information goes back, but I don't
7 know exactly when the federal investigators
8 knew what. So I apologize.

9 Q. So internal FDA memos would be one
10 thing that documents what the FDA was talking
11 about and thinking about at the time, correct?

12 A. Absolutely. I'm sure the
13 Department of Justice, right -- there was a
14 criminal investigation --

15 Q. I'm not talking about the criminal
16 investigation. I'm talking about internal --

17 A. But that's where the promotion --

18 Q. I'm talking about what FDA knew.
19 FDA's records of its own communications with
20 not just Purdue but other manufacturers would
21 be -- would be one source of what it knew?

22 A. Well, I mean, there certainly would
23 be internal FDA documents.

24 Q. Okay.

1 A. And the...

2 Q. DDMAC letters, whether untitled or
3 warning letters, would be another source of
4 information about what FDA knew?

5 A. Correct.

6 Q. Discussions about labeling changes
7 would be another potential source of
8 information about what FDA knew?

9 A. They tend to -- they're very hard
10 to read. Those back-and-forth label
11 indications don't really give you a sense of --
12 unless there's a comment that is written,
13 rarely, about that, it doesn't give you a lot
14 of what they were thinking.

15 Q. So somebody who wasn't there at the
16 time can't really fairly interpret them after
17 the fact. Is that your testimony?

18 A. No.

19 MR. RAFFERTY: Object to the form.

20 A. That's not -- you asked me what FDA
21 was thinking. No one can do -- no one should
22 be able to tell you what FDA was thinking
23 because that's a subjective state. I can tell
24 you what the record reflects.

1 Q. Okay. So you're not going to
2 testify as to what FDA was thinking if you
3 weren't there.

4 MR. RAFFERTY: Object to the form.

5 A. I'm going to answer the questions
6 you ask me the best I can. I'm certainly not
7 going to -- I would advise you not to ask me
8 what somebody was thinking because that's a
9 subjective state of mind.

10 If you ask me about what the record
11 shows and there's a document, I'm happy to talk
12 about it.

13 Q. Okay. So -- but you -- but you're
14 not going to testify to what individuals,
15 reviewers, knew or didn't know unless there's
16 some concrete evidence of that?

17 MR. RAFFERTY: Object to the form.

18 A. I'm going to answer questions that
19 are asked fully, based on the evidence that I
20 have.

21 Q. Okay. And you're not -- you don't
22 have any special training or knowledge that
23 lets you interpret what somebody was thinking
24 at any point in time?

1 MR. RAFFERTY: Object to the form.

2 A. I am not a mind reader, and I would
3 never want to do that in any form of testimony.
4 If you ask me a question, I'll try my best to
5 answer it.

6 Q. And that would be true not just
7 with regard to what FDA was thinking, but it
8 would be true with regard to what anybody at
9 any of the companies were thinking as well?

10 MR. RAFFERTY: Object to the form.

11 A. So obviously the word "thinking," I
12 would agree with you. But I think when there's
13 an objective record -- so I can tell you what
14 is stated, okay --

15 Q. But you're not going to purport to
16 interpret somebody's intent or their state of
17 mind?

18 MR. RAFFERTY: Object to the form.

19 A. I will never go to intent.

20 Q. Okay. When were you first
21 contacted in this case?

22 A. I don't mean to be technical on
23 this. Define "this case," please.

24 Q. Well, to offer an opinion with

1 regard to what we're now calling the opioid
2 litigation.

3 A. So there were -- the reason I'm
4 having some difficulty, Counselor, is, there
5 were some individual cities that I would
6 count -- that perhaps I was consulted with
7 before there was an official MDL. And they may
8 have been merged, and I apologize, I just don't
9 know all the mergers here.

10 So if you asked me officially with
11 regard to the MDL, my guess is it's over a year
12 ago. If you asked me about individual cities
13 or counties, it could be a number of years
14 back, and they could be part of the MDL. So
15 that's why I'm -- I just want to be exact.

16 Q. Is it your understanding that
17 you're a retained expert for any individual
18 city or county not part of the MDL?

19 THE WITNESS: Sorry, how do I go
20 down to...

21 Q. The question was, is it your
22 understanding that you're a retained expert for
23 any individual city or county not part of the
24 MDL?

1 A. I'm having a little difficulty with
2 the word "retained expert." I am trying to
3 think.

4 Q. Is anybody paying you?

5 A. No.

6 Q. Is anybody --

7 A. Well, maybe some day.

8 Q. Do you have any written agreements
9 with anybody outside the MDL?

10 MR. RAFFERTY: Object. Hang on a
11 second. Yeah.

12 I've been letting you go a little
13 bit on this.

14 But to the extent you are -- you
15 may be a consultant that is not a
16 retained -- or that is not a disclosed
17 expert witness, I think that is work
18 product on behalf of those particular
19 parties. And so...

20 Q. Without getting into who the
21 parties are at this point, do you understand
22 yourself to have an agreement to be an expert
23 for any jurisdiction other than the MDL?

24 A. I'm not comfortable answering that

1 without talking to counsel in any of those
2 matters, just because I am not sure the
3 definition of "an agreement." So I just -- I
4 would want to talk to counsel before --

5 Q. Without telling me which any of
6 them were, have you received or reviewed
7 documents at any point prior to when you
8 started reviewing documents for the MDL
9 lawyers?

10 MR. RAFFERTY: I'm going to object.
11 And you have the right not to
12 answer that question as --

13 MS. FREIWALD: I don't think you
14 have a right to tell him not to answer
15 that question.

16 MR. RAFFERTY: I think I have a --

17 Q. And I'm not asking -- I'm not
18 asking identity of anyone. I just really want
19 to know how long you've been looking at
20 documents in the context of litigation, how
21 much it goes past a year.

22 MR. RAFFERTY: And I think --

23 A. It --

24 MR. RAFFERTY: -- that's work

1 product.

2 A. Why don't you guys work it out, and
3 then I can decide. I mean --

4 Q. It's not work product.

5 A. Well, I -- respectfully, I just
6 want would want to talk to counsel in those
7 matters. To be helpful, I may have signed
8 certain protective orders back a while ago.

9 I don't remember actively looking
10 at documents, okay. I'm not saying I was never
11 sent anything. I may -- I think I was sent
12 stuff, but I'm not -- in other matters -- but I
13 would want to -- but I don't think I was
14 actively involved. I think -- I think it
15 would -- to give you the -- it's really the
16 MDL, where, quote, work was done.

17 Q. Okay. And that gets to my
18 question. It was really when you were retained
19 for the MDL that you started looking at
20 documents, correct?

21 A. I think that would be a fair
22 statement. There may have been other documents
23 in the press, other things over the years, but
24 on any serious basis I'm --

1 Q. In any systematically --

2 A. What it took to do this, this is
3 from the MDL database.

4 Q. And this is about a year's worth of
5 work is what you're saying?

6 MR. RAFFERTY: Object to the form.

7 A. Don't hold me exactly to it. It's
8 probably a year plus.

9 Q. What is it that you're looking at
10 that's in front of you?

11 A. Notes. My image sheets.

12 Q. Is it anything that was produced to
13 us?

14 A. These are things that I -- these
15 are cut-and-pastes of documents that I make
16 over a period of time on certain subjects. I
17 don't believe you asked for me to bring
18 anything, but if you wanted to, quote, see my
19 file, for example, here it is.

20 Q. So it was --

21 MR. RAFFERTY: Those are
22 documents -- so you know, the documents
23 are all -- only documents that are cited
24 in his report are on his reliance list.

1 Q. So there are several -- and we can
2 count them later, but there are several very
3 large copies. It looks to me like you have
4 Post-its on them that say things like, General
5 1, General 2.

6 A. That was really just to organize
7 these because I became even a little
8 overwhelmed with my own sheets.

9 Q. And there's handwriting on them,
10 and then they also appear in part to be
11 excerpted copies of some documents that I'm
12 assuming were part of the production.

13 MS. FREIWALD: Is that --

14 MR. RAFFERTY: That's correct.

15 MS. FREIWALD: -- a reasonably
16 fair --

17 MR. RAFFERTY: That's what I --

18 MS. FREIWALD: -- characterization
19 of those?

20 MR. RAFFERTY: That's what I --
21 that's what I understood.

22 Q. And these are things that you're
23 using to assist you in your testimony today?

24 A. These are things that I have with

1 me, and I may -- and I will look at them
2 occasionally if I need to refresh a
3 recollection on a document.

4 Q. Okay. So that --

5 A. As well -- as well as all these
6 binders, as well as binders behind me.

7 Q. Okay. So you're waving your hand
8 at a whole bunch of binders. There have got to
9 be over 20 or more of them. But it's been
10 represented to me -- they're numbered, so
11 somebody could probably tell me how many there
12 are.

13 MS. FREIWALD: Do you know, Parvin?

14 MS. AMINOLROAYA: I don't know off
15 the top of my head.

16 MR. MAGLASANG: 63.

17 Q. 63, I've just been told. Okay, so
18 there --

19 A. And some behind --

20 Q. I'm sorry?

21 A. And some behind the screen.

22 Q. So 63-plus binders. But I've been
23 told that what is in the binders -- and you
24 tell me if I'm wrong or not, please -- are just

1 paper copies of --

2 MS. FREIWALD: Is it his entire
3 reliance list, or is it just what's
4 attached -- what's noted in his
5 footnotes?

6 A. Can I respond to that?

7 Q. Sure.

8 A. So in each binder, it is -- each
9 binder has a tab, it has a paragraph number
10 associated with it, and any document that is
11 cited in the document is behind the tab.

12 There -- if there is a quote,
13 how -- part of cite checking, if there's a
14 quote that's in the report, that quote may be
15 flagged just with a little flag. But that
16 reflects the quote in the -- so I can find the
17 page.

18 Q. So let me see if I can say this a
19 little more simply.

20 Are these documents the footnoted
21 documents in your report as opposed to
22 everything that's in your reliance materials?

23 A. That would be correct. If you add
24 the word "footnoted and body," that would be

1 absolutely accurate.

2 Q. What does that mean, "footnoted and
3 body"?

4 A. In the body of the report. I mean,
5 I think everything is in the footnotes. I
6 don't think there's anything in the body. But
7 everything is in the footnotes, I would --

8 Q. Okay. Okay. It's something that's
9 actually cited in your report?

10 A. Well said, ma'am.

11 Q. Okay. And I've also been told that
12 these documents are not annotated, that there's
13 no handwriting.

14 A. So I would never want to say never.
15 You may be able to find a pen scratch. You may
16 be able to find something circled in there. Go
17 have -- I mean, I have looked at those things.
18 I may have had a pen in hand. I tend not to do
19 that. I tend to scribble on these things. But
20 I leave it, you know -- I mean, I don't
21 think -- I think -- I think you would -- it
22 would be a rare instance if there would be
23 anything in there.

24 Q. Okay.

1 MS. FREIWALD: So we certainly are
2 going to want copies of what Dr. Kessler
3 has brought with him and he's using at
4 the deposition that are the large
5 photocopy documents. And we'll take a
6 look at the binders and see if we need
7 to get a copy of those are not. And
8 people can decide.

9 Q. You stated in your report that the
10 schedules were prepared at your direction.

11 A. Correct.

12 Q. You said something like that. How
13 did that work?

14 A. So I -- those were done all per my
15 specific directions and under my review, with
16 the exception of one schedule.

17 Q. And you said that in your report.
18 So what does that mean? What part of it did
19 you actually do as opposed to having a lawyer
20 or a paralegal or somebody else do it?

21 A. So the -- what I would do is, I
22 would set out specifically -- I would give
23 specific instructions on what I needed to be
24 searched for and put on either a chart -- this

1 is all meant to be factual, objective
2 information that is -- should be
3 non-controverted or -- I mean, I'm not
4 sure it's -- nothing is perfect. I know
5 there's some errors.

6 Q. So turn to -- just so that we can
7 talk about something concretely, turn to
8 exhibit -- schedule 6.

9 A. Sure. Let me just get to it. So
10 that's the DDMAC. Yeah.

11 So what I would -- what I asked was
12 basically to -- this is a summary of --

13 MR. RAFFERTY: I don't think -- I'm
14 just going to object.

15 You don't have to get into
16 conversations that you had with counsel
17 in preparation of anything.

18 MS. FREIWALD: Well, the --

19 MR. RAFFERTY: Rule 26 prohibits
20 discussion about conversations that he
21 had with counsel.

22 MS. FREIWALD: Well, the report
23 says that these were prepared at his
24 direction. So I'm asking how they were

1 prepared.

2 MR. RAFFERTY: And I think you're
3 entitled to ask a general question, but
4 anything further or going into specifics
5 I don't think is appropriate. He put it
6 in the report. That's why I let the
7 questions go the way they have.

8 MS. FREIWALD: Well, I'm entitled
9 to know how much of this is him and what
10 he did, so that's what I want to know.

11 MR. RAFFERTY: I don't -- I don't
12 think you -- I don't think you are. So
13 you can ask, as you have, the general
14 question, and I think he answered it in
15 explanation of what the -- of what the
16 report said.

17 Q. What is it that you asked for?

18 A. I asked for -- what I wanted was
19 information in an objective fashion about --
20 for example, in 6, it deals with DDMAC letters
21 and DDMAC statements back and forth. So if one
22 wanted to talk about -- if you asked me, for
23 example, your question about how many DDMAC
24 letters there were to Purdue or how many notice

1 of -- untitled letters, we should be able to go
2 into this and both agree. And hopefully, after
3 some time, we make sure this is right, we'd be
4 able to answer that question.

5 Q. So do you --

6 A. That's the only purpose of this.

7 Q. Did you use schedule 6 as opposed
8 to the actual letters?

9 A. No, I have the actual letters. I
10 just wanted to have a record here, so if -- you
11 know, if we were ever in back-and-forth and we
12 needed to turn to it, I could turn to this and
13 we could --

14 Q. Why would this be better than the
15 actual letters?

16 MR. RAFFERTY: Object to the form.

17 A. Well, because, I mean, it's one
18 place to look rather than -- I may not be --
19 I've been looking at a lot of documents. I
20 mean, a lot, a lot of documents. And there are
21 documents all over the place. And sometimes
22 when you have a chart that lists all the
23 documents in one place, it's a lot easier to
24 understand what we're talking about, is my

1 experience.

2 Q. Sir, how much time do you believe
3 you spent reviewing documents for this case?

4 A. Tons.

5 Q. What's "tons"?

6 A. A lot.

7 Q. What's "a lot"?

8 A. Hundreds and hundreds of hours.

9 Well, hundreds and hundreds of hours totally,
10 but I spent a lot of time reviewing documents.

11 Q. How -- do you have a record of it?

12 A. Reviewing documents, no.

13 Q. Do you have a record of total time?

14 A. I have -- I've not totaled up total
15 time, no.

16 Q. Do you have a record of how many
17 depositions you actually read?

18 A. I have -- I have searched -- I --
19 all my -- all the depositions are in a hard
20 drive, and I think it would be fair to say how
21 many did I search, because that tends to be how
22 I use depositions.

23 Q. Are there any depositions that you
24 read beginning to end or mostly beginning to

1 end?

2 A. Oh, I'm sure -- I'm sure there were
3 over time. I'm sure there were.

4 Q. Did you read Dr. Wright's
5 deposition?

6 A. Which one?

7 Q. In the MDL?

8 A. I may not have read -- I don't
9 remember which one I've read of Curtis's, but I
10 think there was a number of his depositions in
11 matters, and I'm pretty sure I've read some of
12 them. They're blurring together. They're in
13 the discovery database.

14 Q. Okay. So you don't -- you don't
15 know if you read his testimony in the MDL?

16 MR. RAFFERTY: Object to the form.

17 A. No. I've searched for -- searched
18 for testimony -- his deposition. I don't want
19 to represent that I read the whole thing.

20 Q. Did you read Dr. Fishman's
21 testimony in the MDL?

22 A. I have searched Dr. Fishman's
23 testimony and certain aspects of it, but I
24 don't want to represent that I read the whole

1 thing.

2 Q. Did you read Dr. Haddox's testimony
3 in the MDL?

4 A. Again, same answer. I believe I
5 have searched -- I searched the depositions,
6 and that's the way I dealt with the -- because
7 there was numerous depositions in this and
8 other matters.

9 Q. Did you review the deposition
10 testimony of any sales representatives for any
11 companies in the MDL?

12 A. Yes. There were certainly --
13 actually, there are a whole host of sales
14 representative depositions taken among the
15 years --

16 Q. That was not my question. My
17 question was in the MDL.

18 A. I can't at this point sit here and
19 distinguish in my head which ones were prior
20 matters and which ones was this. But I
21 certainly looked at incentive compensation,
22 where the compensation was tied. There were
23 depositions that I searched for those matters
24 and those were sales reps.

1 Q. What is the basis for the
2 supplemental reliance list?

3 A. I try to be -- things that I looked
4 at or -- things that I looked at subsequent to
5 my report or that I -- I don't know if there's
6 anything that didn't make it onto the original
7 reliance list. I didn't want to walk in today
8 with just additional stuff. So I tried to give
9 you that 24, 48 hours before.

10 MS. FREIWALD: The supplemental
11 reliance list, we'll mark it as
12 Exhibit 2.

13 (Exhibit Kessler-2 marked for
14 identification and attached to the
15 transcript.)

16 BY MS. FREIWALD:

17 Q. My copy is two-sided. Are these
18 documents that you did not read or did not
19 review prior to the production of your report?

20 A. I wouldn't want to -- I mean, these
21 are just Bates numbers. We'd have to look
22 for -- you'd have to show me the document for
23 me to be accurate for me to tell you when I saw
24 it.

1 Q. Well, do you know why -- you know,
2 you produce a report that's 300-some pages and
3 reams of documents. Why are these supplemental
4 materials?

5 MR. RAFFERTY: Object to form.

6 Q. Is it because you looked at them
7 after the report?

8 MR. RAFFERTY: Object to the form.

9 A. It may -- it may be in a number of
10 instances that I found these in the database
11 when I was searching after the report. My
12 guess is, that would be the predominant answer
13 to this.

14 There are some documents that are
15 referenced, as you can see, that were -- there
16 was a Bates number that was zero, mistaken, so
17 they had to add those because it referenced the
18 wrong document on the bottom. But if you're
19 referring to these on the top, these are things
20 that I made sure that I said to counsel, please
21 make sure these are on the reliance list.

22 Q. Did you create that yourself?

23 A. These were done -- this was done at
24 my direction.

1 Q. And the errata sheet, which I'll
2 mark as Exhibit 3, is that something you did?
3 You went through your report and decided what
4 needed to be fixed?

5 MR. RAFFERTY: Object to form.

6 A. In some instances, yes. Much of
7 this is typographicals. What I did ask for --
8 again, I'm going to say with the assistance of
9 counsel --

10 THE WITNESS: And you're going to
11 say, stop.

12 A. But with the assistance of counsel,
13 I asked for cite checking. And sometimes when
14 people do cite checking, you find certain
15 mistakes in quotes. When I asked for things to
16 be highlighted, things get identified as
17 mistakes that are in the report. So I did ask
18 for people to keep track when they
19 cite-checked.

20 (Exhibit Kessler-3 marked for
21 identification and attached to the
22 transcript.)

23 BY MS. FREIWALD:

24 Q. Before issuing your report in this

1 case focused on six manufacturers, did you do
2 anything to investigate the full scope of
3 mistakes or missed opportunities by any number
4 of other entities?

5 MR. RAFFERTY: Object to the form,
6 vague.

7 A. It's a broad question. Can you be
8 a little more specific?

9 Q. I meant it to be a broad question.

10 MR. RAFFERTY: Object to the form.
11 You can answer it if you understand
12 what she's asking.

13 THE WITNESS: Well, I think I
14 understand what she's --

15 A. I certainly gave a good -- a good
16 deal of thought to FDA's role in this. We
17 discussed that initially. So I did that. I
18 tried to gain an understanding of -- even
19 though I'm not -- if there's any distributor in
20 the room, I'm not -- I have no opinions on
21 distributors. You can go take the day off.

22 I try to have some understanding of
23 DEA's role. The database has distributor
24 information. I certainly looked at -- for

1 example, there are documents from the counties
2 on the database. Looked at those.

3 So I looked at a broad range of
4 documents. The scope of the question that I
5 was asked, though, was the manufacturer, so
6 I -- but certainly I think I have some
7 understanding with regard to FDA, certainly
8 with regard to HHS, a limited fashion with
9 regard to how FDA and DEA interacts on
10 legitimate medical need.

11 Q. Did you -- did you look --

12 MR. RAFFERTY: Are you finished
13 with your answer, Doctor? That was a
14 vague question.

15 You said you meant it to be broad
16 and vague.

17 A. But I will say that I tried in the
18 report to focus on the question that I was
19 asked, which focused on the manufacturers. But
20 I -- but I did put it in the context -- the
21 broader context, yes.

22 Q. Were you asked to focus
23 specifically on six manufacturers?

24 A. I believe that was the -- yes. I

1 believe it was the manufacturers that, quote --
2 actually, let me -- let me take that back.

3 "Manufacturers" is probably not the
4 right term. I was focused on certain drugs.
5 Sometimes manufacturers change. So it was
6 really the drugs or which generic drugs. And I
7 tried to list those.

8 If you -- so certain drugs that I
9 was told were the subject of the MDL and
10 certain drugs that were not the subject of the
11 MDL.

12 Q. Do you know how many prescription
13 opioids there are that are outside the scope of
14 your report?

15 A. Are you talking about branded
16 generics or generics or --

17 Q. Any.

18 A. I can -- I have charts here
19 available.

20 Q. Do you -- do you know? Can you
21 sit -- can you tell me what percentage of the
22 opioids on the market you actually looked at?

23 A. In what year?

24 Q. I'm asking if you know, sitting

1 here today, when you thought about the claims
2 you're making -- and you make some pretty
3 sweeping claims -- how big a part of the pie do
4 you know you were looking at?

5 MR. RAFFERTY: Object to the form.

6 A. I looked at a very big part of the
7 pie. I went back to the -- I went back -- I
8 looked at a very big part of the pie.

9 Q. Do you know how many you didn't
10 look at?

11 A. No, because I -- what I did is I
12 actually went back to the raw materials.

13 Q. Do you know how many different
14 products you didn't look at?

15 A. How many different products I
16 didn't look at? I'd have to look again -- I'd
17 have to understand what class and what you mean
18 by "product."

19 Q. Did you review the history of
20 hydrocodone products?

21 A. Did I -- I am not a -- I reviewed
22 some of the history. And actually, I decided
23 not to put it in the report because the report
24 was getting a little long. But I did go back

1 and review hydrocodone, certainly, products and
2 the codeine products. I've looked at that
3 history, but it was not part of the subject
4 matter.

5 Q. It's -- I won't find that
6 discussion in your report, correct?

7 A. You'll have some -- there's some
8 discussion, very brief, that actually I -- I
9 ended up limiting it to just the very small
10 part in the history. But I'm happy to discuss
11 the history.

12 Q. And you didn't look at trends in
13 abuse or misuse of prescription pharmaceuticals
14 outside of the six manufacturers that --

15 A. Oh, I certainly -- I mean, I can
16 sit here -- if you want to talk about abuse
17 trends, I'm happy to spend the next ten hours
18 talking about abuse --

19 Q. That's not in your report?

20 A. Well, but --

21 Q. That's not in your report, is it?

22 A. Well, my report -- again, I'm happy
23 to talk about abuse trends. I'm happy to
24 talk --

1 Q. All I'm asking, is it in your
2 report?

3 A. You asked me whether I looked at
4 it.

5 Q. I asked if it was in your report.

6 A. Okay. So no. My report focuses --
7 well, that's not exactly true. In certain
8 instances there are certain footnotes in my
9 report that go beyond -- for example, in the
10 ADF formulations and what the implications of
11 that for heroin and other compounds. So there
12 are references to that in my report.

13 Q. Did you do anything before issuing
14 your report to review internal documents from
15 any entities other than the six companies?

16 A. Define "entities," please.

17 Q. Either public or private
18 organizations.

19 A. So is -- I mean, the --

20 MR. RAFFERTY: Object to the form.

21 A. I think it's fair to say, yes, the
22 discovery database that I saw had information
23 on a whole range of third parties from JCAHO to
24 the Robert Wood Johnson Foundation. I've

1 looked at those extensively. They were
2 provided in discovery.

3 So there's a whole host of entities
4 that were looked at.

5 Q. Internal documents from DEA?

6 A. Internal documents from DEA? I've
7 looked at -- I've looked at some documents from
8 DEA. I wouldn't think that they're internal
9 necessarily. They tended to be the more public
10 documents from DEA that I saw or DEA
11 presentations that I -- that I saw.

12 Q. What about internal documents from
13 any manufacturer not part of who you're looking
14 at?

15 A. So there were -- there were
16 subsidiaries of your client, for example,
17 Rhodes, others that I looked at in studying the
18 raw materials and the finished products, but
19 they were sort of -- I don't know whether
20 they're separate entities, you would consider
21 them, or they're the same as Purdue.

22 But certainly with Rhodes, I
23 studied Rhodes's manufacture of API. I've
24 looked at, for example, Noramco,

1 Tasmanian Alkaloids. I mean, if you look at
2 the -- if you look at super poppy and the
3 production of super poppy and your client's
4 buying super poppy and the high alkaloid --

5 Q. That's not what I asked. I asked
6 about outside this.

7 A. Yes. Well, that's outside. So
8 that -- if you look at Tasmanian -- the company
9 called Tasmanian Alkaloids that is owned by
10 Noramco that is owned by Johnson -- by
11 Johnson & Johnson, that Tasmanian Alkaloids,
12 for example, fed -- OxyContin would not have
13 been driven without Tasmanian Alkaloids and
14 super poppy. So I looked at that. Those were
15 entities maybe other than the six.

16 Q. So, sir, at the time that you were
17 at FDA, was looking at internal company
18 documents part of anything the agency did?

19 A. You're using internal company
20 documents?

21 Q. Yeah, other than -- yes. You
22 wouldn't look at internal sales and marketing
23 documents, would you?

24 A. No.

1 Q. You wouldn't look at call notes?

2 A. No. That is correct.

3 Q. You --

4 A. We didn't have access to that. FDA
5 would love to have access.

6 Q. FDA doesn't look at draft plans?

7 A. The FDA doesn't look at marketing
8 plans. FDA doesn't look at budget plans. FDA
9 would love to do that. It doesn't have access
10 to that.

11 Q. And none of that is within kind of
12 the skill set of the FDA reviewer?

13 A. Oh.

14 Q. There's no training or experience
15 that you have at FDA in looking at those kinds
16 of documents and interpreting them?

17 MR. RAFFERTY: Object to the form.

18 A. I took marketing in business
19 school. So I'm well-trained. I've been on
20 corporate boards where marketing plans get
21 presented all the time. So I am well-trained
22 in marketing plans.

23 And -- but I can tell -- and the
24 agency certainly understands promotion. Just

1 because it doesn't have -- the FDA has to play
2 peek-a-boo, in essence.

3 Q. So the agency understands
4 promotion?

5 A. Not the -- we could spend the next
6 hour answering that question.

7 Q. Okay.

8 A. I mean, not to the extent -- not to
9 the extent and the sophistication that's shown
10 in this record, right.

11 Q. So --

12 A. The agency has to look for intended
13 use. The FDA sometimes in criminal cases may
14 get access, through DOJ and certain subpoenas,
15 to see certain things. The Office of Criminal
16 Investigations get to see some of this stuff.

17 But FDA is constantly playing
18 peek-a-boo, right, and it's trying to put
19 together a piece because it only has access to
20 certain documents. But the FDA, as you know,
21 has to figure out a company's intended use.

22 So FDA certainly understands
23 marketing plans from intended use. It may not
24 be until the criminal stage, but your

1 company -- the industry --

2 Q. Sir --

3 A. -- doesn't want to turn those
4 things over to the agency.

5 Q. Sir, it's not part of what FDA does
6 to interpret draft plans or internal plans, and
7 then -- and opine on them?

8 MR. RAFFERTY: Object to the form.

9 A. It certainly does to the Department
10 of Justice when -- in any criminal
11 investigation.

12 Q. The FDA.

13 A. I'm talking about the FDA's Office
14 of Criminal Investigations. I can tell you
15 that FDA's Office of Criminal Investigations
16 will certainly look, check --

17 Q. It's not what you did?

18 MR. RAFFERTY: Objection.

19 Let him finish his answer.

20 A. I set up the Office of Criminal
21 Investigations, right.

22 So the issue of -- FDA has to
23 determine the intended use. The Act is
24 written -- as the article intended to affect

1 the structure or function of the body.

2 FDA knows perfectly well that that
3 intended use comes from the marketing plans,
4 the business plans. FDA would love to have
5 that. But the industry doesn't make those
6 available to the FDA, so it's -- FDA has to go
7 find evidence here or there.

8 And then finally, if you're getting
9 into a 2007 event, right, which you got into,
10 then there's subpoena power, and then you could
11 start seeing a bigger picture.

12 Q. So that would be a time where you
13 could see what the activities were?

14 A. No. You can -- you can go -- you
15 can go see these activities when you go to a
16 convention. You can go see these activities
17 when you go online. You can go see these
18 activities when you're talking to doctors.
19 What you don't get to see is, for example, the
20 surveys that the companies do of what doctors
21 are told or the extent of the return on the
22 investment from this activity.

23 FDA is perfectly competent and
24 knows how to handle those documents. It just

1 doesn't get those documents because the
2 industry doesn't turn those over.

3 Q. It's not part of what you would do
4 in the normal course?

5 A. No. FDA certainly looks at
6 intended use and whether the marketing was --
7 it just doesn't get this in all instances, and
8 it doesn't get this until certainly it has
9 subpoena authority.

10 Q. Okay. So let's just break this
11 down a little bit. When a drug is approved,
12 the FDA knows that marketing is going to be
13 part of it, correct?

14 A. Yes.

15 Q. And the --

16 A. Well, no, that's not true. I mean,
17 they shouldn't -- FDA knows what the company
18 tells it.

19 Q. FDA knows that most products today
20 that are branded are going to be marketed in
21 some way?

22 A. FDA assumes that.

23 Q. Okay. And that it's going to be
24 marketed consistent with what the regulations

1 require, consistent with the product labeling,
2 correct?

3 A. No. That's not actually correct.

4 The marketing has to be -- there
5 has to be substantial evidence of
6 adequate and well -- the Act requires that
7 there be substantial evidence based on adequate
8 and well-controlled clinical trials to support
9 the marketing. Now, sometimes as a surrogate
10 for that we can use the term "label" because
11 it's subsumed that it's sometimes the label.

12 But the actual statute requires
13 substantial evidence of adequate and
14 well-controlled trials.

15 Q. To support the label, the product
16 label?

17 A. No, to support the marketing. The
18 actual marketing --

19 Q. Are you testifying that the
20 marketing can be outside the bounds of the
21 label?

22 MR. RAFFERTY: Object to the form.

23 A. Let me just be very clear. The
24 marketing -- marketing -- and I am very sure of

1 this -- that what FDA requires in any
2 promotional activity is that there be a
3 substantial evidence based on adequate and
4 well-controlled clinical trials to support any
5 promotional activity.

6 Now, in general, that is viewed as
7 the same standard for drug approval. And in
8 general, if you want to go make a claim, FDA
9 will say, you need two adequate and
10 well-controlled clinical trials that support
11 that claim.

12 But the standard -- if FDA goes
13 into court, right, the standard is not whether
14 it's in the label. The standard is whether
15 there is adequate and well-controlled clinical
16 trials to support that claim. That's what has
17 to be shown in court under a misbranding
18 charge.

19 Q. FDA knows that drugs today are
20 promoted, correct? Branded products are
21 promoted.

22 MR. RAFFERTY: Object to the form.

23 A. That's not true in all instances.

24 Q. In the overwhelming majority of

1 instances that's true.

2 A. I think that's -- I think that's
3 fair. That's the reality. But there are
4 certain drugs that -- there are certain
5 examples where that is not the case.

6 Q. And they can be promoted to
7 physicians, correct? FDA knows that?

8 A. Sure.

9 Q. And they can be promoted directly
10 to consumers. That's something else FDA knows?

11 A. They -- there's certainly -- yes,
12 FDA knows --

13 Q. And --

14 MR. RAFFERTY: Hang on.

15 A. Well, that's a little complicated.
16 It's not -- it's not --

17 Q. And the FDA knows that there's
18 branded promotion specifically of the product?

19 MR. RAFFERTY: Object to the form.

20 Q. Correct?

21 A. There's branded promotion that --
22 it may not be specific to the product; it may
23 be tied to the product is probably more
24 accurate. It can be color, form, other things

1 that make it branded. It's not necessarily
2 just the product name.

3 Q. And there's -- and there's
4 unbranded promotion that doesn't talk about the
5 product specifically? That's another type of
6 promotion that FDA knows exists and is allowed?

7 A. Unbranded promotion that is false
8 or misleading is not allowed.

9 Q. But generally speaking, when FDA
10 approves a drug, they know that companies can
11 engage in both branded promotion and unbranded
12 promotion related to the disease state or --
13 for the drug?

14 A. That is generally a fair statement,
15 yes.

16 Q. And FDA will -- when a -- when a
17 drug is approved, FDA actually has to approve
18 the launch-related promotion?

19 A. Yeah, that may be a little bit an
20 overstatement. Generally that happens at
21 launch, but sometimes there's material after
22 launch. And I'm not sure -- it's generally
23 asked, it's required to be submitted as part.
24 I'm not sure it has to be approved under the

1 statute, but there --

2 Q. Do you know, sitting here today, if
3 FDA approved the launch-related promotion for
4 any or all of the products about which you have
5 opinions?

6 A. Yeah. I mean, I certainly have
7 looked at that back-and-forth, for example.
8 And I would say, for example, your company
9 submitted certain materials; FDA told your
10 company what it thought; your company fought
11 the FDA; and it -- your company certainly
12 didn't follow what FDA was saying in that -- in
13 that back-and-forth with the FDA.

14 Q. There can be a back-and-forth
15 between the company and the agency, correct?

16 A. There's always back-and-forth.

17 Q. Okay. And whether it's fighting or
18 negotiating or reasonable disagreement, you
19 can't say what was in people's minds, can you?

20 A. I can't -- I can't say that, but I
21 can say that it is striking to me, right, with
22 a controlled substance --

23 Q. Sir, I'm just asking a question.

24 A. I know you're asking a question.

1 What is striking to me is the
2 extent to which your company opposed and didn't
3 listen to what FDA said. Curtis Wright was
4 very clear that he didn't want OxyContin to be
5 used as the drug to start with in non-malignant
6 pain.

7 Q. Sir --

8 A. That record is clear. Your company
9 didn't -- opposed that repeatedly, must have
10 come back four or five times if you look at
11 that discussions, and in the end, you know --

12 Q. Is there any launch-related
13 material in this case that the FDA did not
14 ultimately sign off on?

15 A. I wouldn't want to use the word
16 "sign off." I think that certainly there was a
17 positioning of this -- of your -- of your
18 client's product that was against what FDA was
19 telling you.

20 Q. Did -- do you know, sitting here
21 today, that the FDA, after some back-and-forth,
22 said, we have no further comments on these
23 marketing materials?

24 A. Yeah, I think at the end -- and

1 it's one -- FDA basically -- again, I wasn't
2 there exactly. It seems like FDA gave up after
3 the nth reiteration on this. But I --

4 Q. So this --

5 A. It's hard -- but it was very clear
6 what FDA was saying. They did not --

7 Q. So they --

8 A. They did not want this used except
9 in very limited indications as for, in essence,
10 step two. Curtis --

11 Q. When the FDA says, we have no more
12 comment, on marketing material, at a minimum it
13 shows that they know what those marketing
14 materials are and are not further disagreeing
15 with the use of those marketing materials.

16 A. Again, knowledge is a subjective
17 state of mind that I don't want to get into. I
18 can talk --

19 Q. So you're not prepared to say --

20 MR. RAFFERTY: Would you please --

21 Q. -- that if the FDA says, we have no
22 further comments on these marketing materials,
23 that that means, we have no further comments on
24 these marketing materials?

1 MR. RAFFERTY: Let the record
2 reflect that constantly, counsel is
3 interrupting the witness in the middle
4 of an answer. And I would ask that she
5 stop doing that so that he can fully
6 answer her questions, which, quite
7 frankly, are mainly very vague and very
8 open-ended, and he's trying to answer
9 those questions.

10 Q. When the FDA says, we have no more
11 comments on marketing materials, you're saying
12 that means something other than, we have no
13 more comments on these marketing materials?

14 A. Again, you've got to show me
15 exactly FDA's words.

16 Q. Okay.

17 A. But I mean, I think you can take --
18 you can take that as what the English
19 language -- I mean, as what it sounds like.

20 Q. Okay.

21 A. The question is what these
22 materials are. If FDA says things prior to
23 that, it means that it has -- you should take
24 into account the comments that were made

1 previously.

2 Q. Okay. Do you agree that at all
3 times FDA has maintained that prescription
4 opioids can be an important therapeutic option
5 for pain patients?

6 MR. RAFFERTY: Object to the form.

7 A. I can tell you, sitting there in
8 1994, I would not have stated it the way you
9 just stated. I think that is vague. It's an
10 overstatement. It's not having fair balance.
11 I think it would be -- I think that statement
12 would be misleading.

13 Q. Has FDA made that statement?

14 MR. RAFFERTY: Once again, counsel
15 is interrupting the witness. Let him
16 finish.

17 A. I can tell you, when I made the
18 statements and when I instructed the agency to
19 make statements in my name on Duragesic, that
20 that was not -- that would not be the sum and
21 substance of what I said with regard to
22 Duragesic.

23 Q. FDA as an agency has been on the
24 record saying that?

1 MR. RAFFERTY: Object to the form.

2 A. If you want to show me a specific
3 comment, quote, I'd be happy to look at it.

4 FDA -- again, I can tell you when I
5 was at the agency, I was very specific. And as
6 I read you, that what I said was -- I'm happy
7 to read it again, right -- but that opioids, or
8 in that case, Duragesic was important for
9 cancer pain, and it might be useful in some
10 patients. But I certainly would not want --
11 the import of what we were saying to the public
12 in 1994 was not that statement, nothing that
13 broad.

14 Q. I --

15 A. And that's where -- making
16 statements like that, right, without saying
17 that -- I mean, opioids are the -- are probably
18 the most addictive substance. To make that
19 statement in isolation and not to say that
20 opioids are the most powerful, addictive
21 substance that we have or among the most
22 powerful addictive substances that we have --
23 to make that statement would be irresponsible
24 to say that alone and put a period after that.

1 Q. Sir, I'm just going to be clear,
2 I'm going to ask you a bunch of questions.
3 They're all going to relate to after you left
4 the FDA and based upon your review of the
5 record, okay?

6 A. But --

7 Q. I just --

8 A. That's fine. But just so you know,
9 my review of the record -- for example, what
10 I'm telling you in 1994 is part of the record.

11 Q. Okay. I'm going to limit my
12 questions, so we're clear, to the time period
13 after you left FDA. All right?

14 A. You can limit your question to
15 however you'd like to, of course.

16 Q. And just so I'm clear, have you
17 seen statements from FDA, not necessarily in
18 isolation, that prescription opioids can be an
19 important therapeutic option for pain patients?

20 A. You'd have to show me the specific
21 statements. I've seen a lot of statements and
22 a lot -- there's been a lot of testimony. It
23 sounds like it may be the first half of a
24 sentence, you know, but I can't believe it's

1 the only thing that would be said.

2 Q. And have you seen statements in
3 your review of materials that FDA has
4 maintained that prescription opioids have a
5 role for patients with both cancer and
6 non-cancer pain?

7 A. Again, that kind of statement would
8 be a general statement, but it would probably
9 be put in context as -- I mean, for example,
10 again, in certain patients, FDA believes --
11 again, and I should point this out, I mean,
12 sitting here today, there is -- there is no
13 adequate and well-controlled trial for chronic
14 use. So it's hard to make that statement, but
15 FDA's been going along with this, right, but
16 there are no adequate and well-controlled
17 clinical trials supporting chronic use.

18 Q. Sir, my question was cancer and
19 non-cancer pain. FDA has taken the position
20 that prescription opioids have a role for
21 patients with both cancer and non-cancer pain.

22 A. I said that in 1994, but I didn't
23 say it the way you just said it.

24 Q. And FDA has taken the position that

1 it would not distinguish between cancer and
2 non-cancer pain --

3 A. Let me just say --

4 Q. -- in the indication?

5 A. Let me just add to the previous
6 question. That statement, for example, if you
7 go back and look specifically at what your
8 company was told, okay, that would be an -- not
9 only an inartful -- a non -- not artful
10 statement, it would be wrong.

11 FDA was -- your company was told
12 specifically, right, that opioids did not have
13 a role in diseases in non-chronic -- in
14 non-cancer pain for things like back pain and
15 osteoarthritis. So that -- so that would be an
16 incorrect statement.

17 Now, FDA you can find statements
18 all over that are general boilerplate
19 statements. But if you look precisely, your
20 company was told that it did not have a role in
21 chronic back pain -- in routine chronic back
22 pain or osteoarthritis.

23 Q. FDA has never been willing to limit
24 the use of opioids just to cancer pain.

1 MR. RAFFERTY: Object to the form.

2 A. It certainly did.

3 Q. Okay.

4 A. I mean, look at the label for --

5 Q. All opioids generally?

6 A. Hold on a second. Look at the
7 label for Actiq. It limited it to cancer pain.
8 The company didn't, but FDA did. So --

9 Q. So there's some opioids that FDA
10 has specifically limited to cancer pain and
11 then others that -- where it has not been
12 willing to limit it to cancer pain?

13 MR. RAFFERTY: Object to the form.

14 A. So if you look historically --
15 remember I told you that I acted on Oralet, and
16 that that product, I put into place very
17 specific REMS on that product. So that that
18 tradition carried over with that same lollipop.

19 But you are -- it's fair to say
20 that if you look over different periods of
21 time, there are certain inconsistencies,
22 because the manufacturer owns the label, right.
23 There are inconsistencies between these labels.

24 Q. Sir, the FDA has in some instances

1 limited certain opioids to use in cancer and
2 has been -- and has been public in saying, with
3 regard to many prescription opioids, it will
4 not limit them as to just cancer.

5 A. I think that that's -- that
6 statement is -- while maybe it's -- one level
7 you can view it as not wrong, it's really
8 misleading --

9 Q. Okay.

10 A. -- because FDA was very clear that
11 it was -- it was limiting non-cancer pain too.
12 It was -- FDA wanted and FDA's position,
13 because I -- and I know this -- FDA's always
14 tried to walk a balance to try to make sure
15 that it makes available, right -- I mean, if
16 you have a crushed spine, right, and you don't
17 have cancer, right, but if you have a crushed
18 spine, right, FDA wants to be able to make sure
19 that patient can be taken care of.

20 So the reason why FDA has left this
21 door open a little on non-cancer pain was to
22 take care, as I said, these instances where
23 opioids can play a role, even if there is not
24 clinical trial evidence. But that exception

1 should not be viewed as -- and should never be
2 viewed as the rule or the way you're stating
3 it.

4 MR. RAFFERTY: Ms. Freiwald, we've
5 been going for almost two hours. Can we
6 get to a point where we can take a
7 break?

8 MS. FREIWALD: Yeah, we can take a
9 break.

10 MR. RAFFERTY: Thank you.

11 VIDEO OPERATOR: 11:23. We are off
12 the video record.

13 (Recess from 11:23 p.m. until
14 11:46 p.m.)

15 VIDEO OPERATOR: 11:46, we are on
16 the video record.

17 BY MS. FREIWALD:

18 Q. Sir, there are regulations that
19 determine what documents a company submits to
20 the FDA as part of the drug approval process,
21 correct?

22 A. Yes and no.

23 Q. Would you agree there are
24 regulations that determine what documents --

1 what types of documents the -- a company
2 submits as part of the drug approval process?

3 A. Yes and no.

4 Q. Okay. What is the "no" part?

5 A. So for example, there are
6 certifications that are made to the agency
7 where a company has to notify the agency of new
8 information, new safety information. That may
9 take many different forms. What that document
10 is, what an inspector may ask for, that
11 specific document may not be specified in the
12 regulation.

13 Q. Categories of documents that are --
14 and I'm asking about prior to drug approval
15 right now, okay? So prior to drug approval,
16 there are certain types of information that,
17 pursuant to regulation, companies submit to the
18 FDA?

19 A. So your question had two different
20 components. You talked about both types of
21 information and then documents. Can you
22 separate that out?

23 Q. Well, I'm trying not to get hung
24 up, sir, because we only have a certain amount

1 of time together. So I'm trying to not get
2 hung up on minutia when I think the spirit of
3 my question is something that I would think, as
4 prior Commissioner of the FDA, you probably
5 understand and we probably don't need to piddle
6 over.

7 So there are regulations that set
8 out the framework for what companies submit as
9 part of the drug approval process?

10 MR. RAFFERTY: Object to the form,
11 move to strike the preamble.

12 A. So there --

13 Q. It's a yes or no question.

14 MR. RAFFERTY: No, he can answer
15 the question.

16 Q. It's a yes or no question. Are
17 there or are there not?

18 MR. RAFFERTY: No, answer the
19 question as you need to.

20 A. So I studied this, I've lived this,
21 I've enforced this over 40 years. There is an
22 iterative process, and the company may -- the
23 FDA may be asking for documents in certain
24 instances or types of information that -- in

1 one company that it may not ask in another
2 company.

3 So it is not -- I mean, the goal,
4 okay, is, I think it would be fair to say, that
5 information that goes towards safety and
6 effectiveness -- very broad, right -- I mean,
7 this is within the purview. But within that
8 there are thousands of different types of
9 documents, types of information. So it's
10 just -- it's an iterative process, I think
11 would be an accurate way to say it.

12 Q. Okay, fine.

13 So as the FDA is reviewing an NDA,
14 an application for approval, there is an
15 iterative process of review. Is that fair?

16 A. Yeah. So I --

17 Q. Okay. Is that fair?

18 A. Let me answer that question.

19 It was fair. And it was especially
20 fair with regard to the pilot drug division,
21 which was a little bit of an exception from the
22 normal review process.

23 Q. I'd like to talk about that. Not
24 right now, but I promise you we will talk about

1 it.

2 A. I look forward.

3 Q. And as the FDA goes through its
4 review, it can go back to a manufacturer and
5 ask for additional information, correct?

6 That's one thing it can do. I'm not saying
7 everything, but it's one thing it can do.

8 A. Yes.

9 Q. Another thing it can do is tell a
10 manufacturer that it's not satisfied with the
11 quality of a study?

12 A. Not quite that simple, but in
13 general, I'm sure the general point has
14 validity.

15 Q. It can go back to a manufacturer
16 and say that it's not satisfied with the
17 quantity of studies that have been submitted?

18 A. In the end the agency can approve
19 or not approve. That's really what it can say.
20 It can share that information or not. But the
21 decision is really under the statute of whether
22 to approve or not approve.

23 Q. So the agency can say to a
24 manufacturer that the agency believes the data

1 submitted is not sufficient and the drug will
2 not be approved on the strength of the
3 submission as it has it at that time?

4 MR. RAFFERTY: Object to the form.

5 A. Not exactly. I mean, for example,
6 in a number of these instances the drugs were
7 only approved based on -- consistent on certain
8 other things, on certain risk maps the
9 agency -- so it was things to come.

10 Q. I'm not trying to be exclusive in
11 my question. I'm -- I'm --

12 A. I'm just trying to be accurate.

13 Q. I'm engaging in an iterative
14 process with you.

15 A. I'm happy to do that.

16 Q. So just so we're clear, when I say
17 "the agency can," I'm not suggesting that it's
18 the only thing the agency can do; it's just one
19 thing the agency can do.

20 So let's try to tick off a list,
21 and if I've missed some things, you'll tell me,
22 okay?

23 A. Okay.

24 Q. So one thing the agency can do is

1 go back to a manufacturer and say, we're not
2 satisfied with the quantity or quality of the
3 data we've seen so far. We're not going to
4 approve your product.

5 A. Fair.

6 Q. Another thing it can do is say,
7 we're not satisfied at this point, but if you
8 would do something additional, we will look at
9 it, and then perhaps we will be able to approve
10 your product. And they can define what that
11 additional something is.

12 A. Leave off the last part of your
13 sentence, that we'll approve the product, but
14 they certainly, say, could make suggestions and
15 they would say they would look at it, yes.

16 Q. Right. Right. Well, I said, if
17 they're satisfied.

18 A. Yes.

19 Q. Not that they will necessarily
20 approve the product.

21 A. Yeah, you're saying what the agency
22 would say. So -- but I'm just saying, the
23 agency will say, if you do so, we'll look at
24 it.

1 Q. Okay. They don't make any advance
2 promises to a manufacturer that they're going
3 to approve a product.

4 A. Well said.

5 Q. And another thing the agency can do
6 is say, we will approve your product but
7 subject to you doing some further work
8 post-approval, correct?

9 A. Yes.

10 Q. And that further work can be a
11 requirement of additional studies?

12 A. Or risk management plans, yes,
13 correct.

14 Q. Okay. So I'm just taking it one
15 thing at a time.

16 A. Correct.

17 Q. One thing the agency can do is
18 require manufacturers to do additional
19 randomized controlled clinical trials after
20 approval, correct?

21 A. Certainly under the accelerated
22 approval regulations, that would be correct.

23 Q. Another thing they can do is
24 require the manufacturer to engage in

1 epidemiological studies after approval?

2 A. There can be phase 4 commitments.

3 Q. Another thing they can do is impose
4 additional risk management requirements on the
5 product, correct?

6 A. Again, today that's true. That was
7 not true at all times.

8 Q. Okay, fair enough. So --

9 A. I mean, again, simply put, it
10 wasn't -- the authority may have been murky.
11 We did it on Oralet. The authority became
12 clearer afterwards.

13 Q. Would you agree with me that as of
14 2001, at least, the FDA had the ability to tell
15 manufacturers that they wanted to see
16 additional risk management programs as part of
17 continued approval of drugs?

18 A. Going back to drugs that are
19 already on the market or drugs coming to the
20 market?

21 Q. In this case I'm going to say a
22 drug already on the market.

23 A. No. So that becomes -- that's a
24 whole different kettle of fish.

1 Q. Would you agree with me -- and I
2 don't want to get too deep into Purdue -- but
3 that as of 2001, the agency said, we're going
4 to want you to take on additional risk
5 management, and that that was going to be part
6 of the obligation?

7 A. There was a series of advisory
8 committees and a series of back-and-forth over
9 a period of several years around that time
10 period, 2001 and 2002, where those things were
11 discussed, yes.

12 Q. Are you aware that as of 2001,
13 there were additional risk management
14 commitments?

15 A. There were risk management
16 commitments beginning -- I'm not sure exactly
17 what they were called -- they were called
18 different things at different points in time,
19 and there were different supplemental things --
20 it was at different points in time.

21 Q. So today we refer -- "we," the
22 agency, refers to its risk management programs
23 as REMS, correct?

24 A. That was specifically codified in

1 statute.

2 Q. Correct. And that's 2009?

3 A. Fair.

4 Q. Something like that? And --

5 A. It was 2007. It was FD --

6 Q. 2007?

7 A. Well, the statute was FDAAA 2007
8 where the agency sought that authority and got
9 that authority specifically.

10 Q. Okay. So 12 years ago, the agency
11 had the REMS authority, correct, as REMS? We
12 started calling it REMS?

13 A. Correct.

14 Q. And before that, there were risk
15 management plans that the agency, in
16 circumstances where it thought necessary,
17 required of manufacturers, and they were called
18 risk management plans or something else?

19 A. Correct.

20 Q. Substantively, however, the
21 elements of those risk management plans often
22 looked a lot like what the REMS look like
23 today?

24 MR. RAFFERTY: Object to the form.

1 A. Yes and no.

2 Q. Okay. They had different
3 components. Is that fair to say?

4 A. Fair point.

5 Q. And is it fair to say that the
6 components of those risk management programs
7 could vary drug to drug, depending upon what
8 the agency considered to be the need under
9 particular circumstances?

10 A. But as you know, there were
11 class-wide REMS, so that -- so that probably
12 is -- again, you can put that in your question
13 somewhere.

14 Q. I'm using "drug to drug" loosely.
15 So yes, sometimes the specifics the agency
16 might think apply to a broad class of drugs,
17 correct?

18 A. Right.

19 Q. And sometimes there would be
20 requirements imposed just on an individual
21 manufacturer, either because the drug wasn't
22 part of a broader class or because the agency
23 perceived there to be intraclass variation?

24 MR. RAFFERTY: Object to the form.

1 A. Yes.

2 Q. Okay. And even before the formal
3 risk management plans, the FDA functionally, by
4 its ability to not approve a drug, could say to
5 a manufacturer, we're going to require you to
6 do more than just have --

7 A. I did that specifically in Oralet.

8 Q. Great.

9 And essentially because the FDA can
10 always just say, we're not approving your drug,
11 the manufacturers are in a situation where, if
12 they -- if they can't give the agency what they
13 want, their drug may not get approved?

14 MR. RAFFERTY: Object to the form.

15 A. So you're -- what you're -- what
16 you're mixing up, Counsel, is -- and that's why
17 I asked you whether you're dealing with
18 pre-approval or post-approval, right. So it --

19 Q. Let's talk pre-approval for
20 starters.

21 A. Well, let me just finish my answer
22 just so the record is clear.

23 So as you know, for example, you
24 took me through, your drug was -- your client's

1 drug, one of them was approved in '95, '96, and
2 then you talked about REMS in 2001. So what
3 the agency --

4 Q. I actually didn't talk about REMS
5 in 2001 because REMS didn't exist.

6 A. I'm sorry. You talked about -- I'm
7 sorry. You talked about risk maps and then we
8 talked about REMS later on, right.

9 But for example, the authority the
10 agency had about not approving, that leverage
11 existed before your drug was approved. Once
12 your drug -- or anyone's drug is approved, the
13 burden shifts to the agency.

14 And what you will see, again, from
15 counsel and FDA counsel, right, and what you
16 saw here is the ability to say, I'm not going
17 to approve your drug.

18 FDA missed that opportunity. So
19 the drugs are already on the market. So the
20 burden then falls to the FDA.

21 So this notion of just, well, we
22 can just say we're not going to approve it,
23 that all-being authority that you just gave to
24 the FDA didn't exist in 2001, et cetera.

1 Q. So let's take it in pieces.

2 So prior to approval, you will
3 agree with me that the FDA can say just, no,
4 we're not going to approve your drug, correct?

5 A. Based on statutory -- it has to --
6 it has to have a statutory basis, a reasonable
7 basis, to do that.

8 Q. Okay. After approval, the FDA can
9 say, we're going to engage in a process to look
10 at whether we think you can continue to market
11 your drug, correct?

12 A. A much higher burden.

13 Q. Higher burden, but they still have
14 that authority, correct?

15 A. Well, the FDA could go in and it
16 could affirmatively -- well, understand what
17 would have to happen, right.

18 Q. They could have a review process?

19 A. Okay. I mean, you can have -- you
20 can review as much as you'd like, but the,
21 quote, taking the drug off -- my only point is
22 that taking the drug off the market, right, is
23 not as simple, right, and it is not that kind
24 of threat. And that's one of the problems

1 because FDA feels ham -- somewhat its hands are
2 strung to a much greater extent once a drug is
3 on the market than prior to being on the
4 market.

5 Q. Not as simple because there needs
6 to be a review process about whether it's the
7 appropriate decision or not?

8 A. No. That's -- what FDA knows is,
9 once a drug is on the market, if it's going to
10 require something, right, and it knows it's
11 going to insist on something it has -- FDA
12 doesn't have the authority, for example, to
13 compel, prior to 2007, a change on the label.

14 So it knew that it would have to go
15 in order -- into court and it would have the
16 burden, right, of showing that something -- not
17 was safe, but was unsafe. And, I mean, it's a
18 much higher -- it's a shifting of the burden
19 post-approval.

20 Q. Is it your testimony that, prior to
21 2007, the FDA did not have the authority, if it
22 chose, to withdraw approval of a drug?

23 A. I never testified to that.

24 MR. RAFFERTY: Objection.

1 Q. Because that's true, right?

2 A. No, I'm sorry.

3 Q. Even at all times --

4 A. No. No.

5 Q. I just want to be clear on
6 something.

7 A. FDA can't just withdraw a drug.

8 Q. It can make a determination that
9 the -- that the -- that the drug cannot
10 continue to be marketed as safe and affected --
11 as safe and effective as labeled? It can make
12 that determination and compel -- and compel --

13 A. Only a Court can compel at that
14 point. So, I mean, that's the problem.

15 Q. What is the authority for that?

16 A. I mean, it's 40 years of food and
17 drug law.

18 Q. Is there a place -- is there a
19 document or a regulation that you can point me
20 to?

21 A. It's a -- if you read the statute.
22 I mean, the statute is constructed in such a
23 way that gives the agency the authority under
24 505 to approve an application. If --

1 Q. And to withdraw --

2 MR. RAFFERTY: Let him finish the
3 answer.

4 A. Just so you know, if you want to
5 withdraw an application, there are regs to do
6 that, but the hoops the agency has to go
7 through -- there are hearing processes that are
8 much more extensive post-approval than
9 pre-approval.

10 Q. Okay.

11 So if you read the statute, the
12 statute is constructed in such a way that gives
13 the agency the authority under 505 to approve
14 an application. Just so you know, if you want
15 to withdraw an application, there are regs to
16 do that.

17 But there are more hoops?

18 A. Yeah. I mean --

19 Q. Okay.

20 A. -- you can say there's an imminent
21 hazard, but I have to prove --

22 Q. But --

23 A. -- certain things. I can only --
24 that ability to compel ultimately -- because

1 I've been in that situation. If you want to
2 pull a drug that's already on the market,
3 right, I mean, I can talk to the CEO, but if
4 the CEO says, no, right, that's going to end up
5 in court.

6 Q. It's more to do, but it can be
7 done, right? It's within the agency's
8 authority?

9 A. You can't compel.

10 MR. RAFFERTY: Objection.

11 Q. Okay.

12 A. It doesn't have the authority to
13 compel a manufacturer to do that.

14 Q. Okay. Literally to compel.

15 But the agency can go through a
16 process, and there can be a vote and a decision
17 that the drug should no longer be licensed.
18 And the agency has done that, correct?

19 A. No, no. There's no such thing as a
20 vote.

21 Q. It's even done that with regard to
22 pain medications, hasn't it?

23 MR. RAFFERTY: Object to form.

24 A. It has -- it has pulled -- it

1 has -- most of these things are done, right,
2 just so you know, a back-and-forth between -- I
3 get on the phone -- I mean, I've been there,
4 right. I get on the phone with the CEO and I
5 say, I may -- I need you to pull this, right,
6 but I don't have the authority to compel.

7 Q. Okay. But you've gotten on the
8 phone with CEOs of pharmaceutical companies and
9 said, I need you to pull your drug.

10 A. Right.

11 Q. And you can do that. And any
12 Commissioner could do that.

13 A. I can -- the First Amendment right
14 still exists, but I don't have the authority to
15 order that.

16 Q. And in fact, drugs have been --
17 whether you want to call it recalled or
18 withdrawn --

19 A. The --

20 Q. -- from the market -- just let me
21 finish my question -- from the market as a
22 result of a process whereby the FDA makes it
23 clear that that's what it wants to have happen?

24 MR. RAFFERTY: Object to the form.

1 A. Yes and no.

2 Q. Okay. So -- and in fact --

3 A. If a company decides to go along,
4 it may say after that phone call -- it may pull
5 the drug.

6 Q. Or it may take some time. But
7 eventually it can happen.

8 A. It certainly -- well, a CEO can
9 stop selling the drug tomorrow.

10 Q. But the CEO can also stop selling
11 the drug, not because the CEO wants to, but
12 because it's very clear that's where the FDA is
13 headed?

14 MR. RAFFERTY: Object to the form.

15 A. The CEO can make any decisions the
16 CEO wants.

17 Q. In fact, the FDA has done that in
18 the area of pain drugs other than opioids,
19 haven't they?

20 A. What's "that"?

21 Q. They have compelled the withdrawal
22 or the removal from the market of pain
23 medications other than opioids.

24 A. Again, you're using a -- the word

1 "compel," and I'm not sure I would agree with
2 the word "compel." You'd have to look at the
3 actual letter in the -- I mean --

4 Q. You know, sir, don't you --

5 A. Hold on a second.

6 Q. -- that there are --

7 (Simultaneous speaking.)

8 MR. RAFFERTY: Let him finish his
9 answer, please.

10 A. Okay.

11 Q. I'm not going to use "compel" in a
12 technical way.

13 A. Well, I --

14 Q. I'm going to use it in a common
15 sense way, because I think we both know that
16 the agency has used its authority, whether --
17 in any number of ways. People take the FDA
18 pretty darn seriously, don't they?

19 MR. RAFFERTY: Object to the form.

20 Q. So if --

21 A. Some do; some don't.

22 Q. Well, the FDA has surely used its
23 authority, including with regard to pain
24 medications other than opioids, to effect

1 withdrawal of products.

2 MR. RAFFERTY: Object to the form.

3 A. Different -- as you know, after
4 2007, different points in time, different
5 statutory authorities were given to the agency.

6 Q. And in fact, we've talked -- we're
7 going to talk mostly about opioids today, but
8 the agency was quite effective at taking some
9 non-opioid pain medicines off the market in the
10 mid-2000s. Isn't that true?

11 MR. RAFFERTY: Object to the form.

12 A. Can you give me an example of what
13 you're talking about?

14 Q. Bextra.

15 A. I'm not here -- I'm not here to
16 talk about specific other compounds. I get --

17 Q. You know that Bextra is a Class II,
18 right?

19 MR. RAFFERTY: There has got to be
20 an end to the interruptions.

21 MS. FREIWALD: Well, I --

22 MR. RAFFERTY: No, but there needs
23 to be.

24 MS. FREIWALD: We have a limited

1 amount of time.

2 MR. RAFFERTY: That doesn't allow
3 you to interrupt the witness.

4 MS. FREIWALD: Well, I have a right
5 to get an answer to my question.

6 MR. RAFFERTY: You're right. And
7 he is answering your question.

8 MS. FREIWALD: So he said he
9 doesn't -- he's not going to talk about
10 other opioids, but I -- so I'm going to
11 move on.

12 A. Class II is not an opioid.

13 Q. I'm sorry. He said he's not --
14 he's not going to --

15 A. I just --

16 Q. I meant to say you're not going to
17 talk about other products -- other products. I
18 misspoke.

19 A. I'm happy to talk about other
20 products. But if you're making a statement
21 that FDA compelled Bextra, let's put in front
22 of me -- because I want to be exact -- and I'm
23 sorry I'm just -- I may be -- I don't mean to
24 frustrate you if I'm too precise. But you used

1 the word "compelled," right.

2 The majority of withdrawals that
3 happened in the 2000s, right, were the
4 result -- and I'm pretty sure this was the case
5 with some of the high profile drugs in the
6 early 2000s -- where the company ultimately
7 voluntarily decides to pull the drug.

8 I am not aware of any formal
9 rule-making or administrative hearings that
10 these drugs went to or any court actions where
11 there was an order to compel in the early
12 2000s.

13 Q. Fair enough. I'm going to try to
14 find some language where you don't feel like
15 I'm using "compel" in that kind of literal,
16 court-ordered way. So I'll stipulate to that.

17 I'm -- what I am saying is, there
18 are examples in the 2000s of the FDA actively
19 working to get certain pain medicines off the
20 market, and that happened.

21 A. Yeah, I'd have to -- I'd want to go
22 back and review the record. You obviously have
23 Vioxx. You have Bextra. There are a number of
24 drugs. I'd want to review the exact history to

1 see whether it's -- whether I would agree with
2 your statement.

3 In general, I can tell you, because
4 I've been there and I've had, again, other
5 counsel, FDA counsel -- it should just be very
6 clear that once a drug is on the market, right,
7 that all-knowing authority that you're trying
8 to give the FDA just doesn't -- it's not the
9 world that exists.

10 Q. I'm not saying -- I'm not arguing
11 with you as to whether there's a different kind
12 of set of circumstances post-approval from
13 pre-approval. I will agree with you on that,
14 okay?

15 A. I think the -- the last one I think
16 the agency --

17 Q. There's no question. There's no
18 question pending. I didn't ask you a question.

19 A. Okay.

20 Q. So that's clear on the record. I'm
21 not trying to say that the world is exactly the
22 same pre-approval as post-approval, okay?

23 A. Right.

24 Q. But whether you call it a compelled

1 recall or a voluntary withdrawal or something
2 in between, there are examples of pain
3 medicines coming off the market as a result of
4 FDA scrutiny and pressure, outside of the
5 opioid class.

6 A. I'd want to go back --

7 MR. RAFFERTY: Object to form.

8 A. The last -- the last one that I
9 remember -- last drug I remember coming off,
10 and people can remind me, was phenformin. I
11 mean, the authority that the agency had -- and
12 that was not a pain medicine. But the --

13 Q. That's not my question. I asked --

14 A. No, let me finish.

15 Q. No. I have a right --

16 A. I'll tell you what your question --

17 Q. Look, sir --

18 MR. RAFFERTY: He's answering your
19 question.

20 MS. FREIWALD: No.

21 MR. RAFFERTY: You asked a very --
22 (Simultaneous speaking.)

23 A. I'm answering the question.

24 Q. No, you're not. No, you're not. I

1 asked --

2 A. The last authority the agency
3 had -- the last --

4 Q. Sir, with all due respect, I did
5 not ask you about the history or the last thing
6 that they --

7 A. No, but --

8 Q. I didn't ask you ---

9 A. But you used certain standards.

10 Q. No. I'm going to read my
11 question --

12 (Simultaneous speaking.)

13 A. -- like compelled -- go ahead. You
14 asked about compelled and voluntary.

15 Q. I'm going to read my question --

16 (Simultaneous speaking.)

17 MR. RAFFERTY: The court reporter
18 can't take you down.

19 (Reporter interruption.)

20 Q. Sir, I'm going to read my question
21 back. And if you are right, then you'll go
22 ahead and answer. And if I'm right, I'm going
23 to ask you to go ahead and answer consistent
24 with my question.

1 Whether you call it a compelled
2 recall or a voluntary withdrawal or something
3 in between, there are examples of pain
4 medicines coming off of the market as a result
5 of FDA scrutiny and pressure, outside of the
6 opioid class. That's correct?

7 A. No. I don't think -- the spectrum
8 that you give, compelled recall or voluntary
9 withdrawal, if -- I mean, the standard on
10 withdrawal, okay, as I remember the statute --
11 I'd want it in front of me to refresh my
12 memory -- is imminent hazard, right?

13 So that's the standard on
14 compelled -- on your compelled. It's -- I
15 mean, so that's the kind of standard one would
16 have to -- and I -- and I am -- I know that
17 both Bextra and Vioxx were not done under the
18 imminent hazard authority. So I would have to
19 go back and review the authority to which
20 you're ascribing and we'd have to determine
21 that.

22 I'm just not prepared -- I mean, I
23 just didn't do my homework to tell you exactly
24 under what authority you're saying FDA, in

1 essence, pressured or required, or the history.

2 I'm not -- I can't agree with that.

3 Q. Okay. Okay.

4 MS. LEVY: On behalf of the
5 subsequent defendants that are entitled
6 to question this witness on the record,
7 I'm going to object to the continuous,
8 obvious filibustering and request on the
9 record that Dr. Kessler be instructed to
10 please try to keep his answers succinct
11 and direct and responsive to the
12 question asked.

13 I believe we are being prejudiced,
14 for the other defendants who have
15 significant questioning for this
16 witness. And the failure to be able to
17 get a short, direct answer to a question
18 is materially prejudicing us, and we
19 request from the witness and from
20 counsel that the witness be instructed
21 to please give short and clear answers
22 to the questions.

23 MR. RAFFERTY: Well, we have a
24 fundamental disagreement as to that, and

1 I disagree wholeheartedly. I think the
2 questions are open-ended, vague. Most
3 of the time there's no time frame given.
4 There's all these generic, open
5 statements being made. And the witness
6 has a right to explain why his position
7 is what it is.

8 MS. FREIWALD: No, sir. And we
9 actually just demonstrated that. The
10 witness was so clearly not answering a
11 question I asked.

12 Q. So we're going to -- so can we
13 agree that Bextra was a Class II?

14 A. I believe so.

15 Q. And can we agree that it was -- it
16 was for pain? It was a pain medication?
17 That's what Class IIs were. They're one of the
18 types of medicines that are used for pain.

19 A. It was a nonsteroidal, yes.

20 Q. Okay. It was -- it is one of
21 the -- nonsteroidal anti-inflammatory drugs are
22 one category of drug that is used for pain
23 management, correct?

24 A. And you have to give me the -- if

1 you give me the label, we can -- I can be sure
2 that --

3 Q. Are you really seriously going to
4 tell me that you don't know that NSAIDs are
5 used for pain management?

6 A. No. But I just want to be sure
7 that the label doesn't include other things.
8 That's what I wanted to be sure --

9 Q. I'm not asking you to read the
10 label, sir, here. I'm asking you just in kind
11 of normal English whether you're prepared to
12 say that you know that NSAIDs are used for pain
13 management?

14 A. Yes. But NSAIDS could -- I mean, I
15 just wanted --

16 Q. That's all I want to know.

17 A. Yes, among other things.

18 Q. Okay. And that was a drug that
19 came off the market in the mid-2000s because
20 there were questions about whether the
21 risk/benefit profile of that drug continued to
22 be sufficient to sustain its continued
23 marketing?

24 A. I haven't studied that of late, so

1 I can't testify specifically. I'm happy to go
2 back and do that homework and look at that.

3 Q. So is it your testimony that,
4 sitting here today, you can't testify to how
5 many times the FDA or under what circumstances
6 the FDA has either compelled or managed to
7 obtain, through some kind of mutual agreement
8 with a company, the withdrawal of a product for
9 pain medicine -- for pain management?

10 A. So I think I told you, I mean, in
11 my testimony that the one instance where there
12 was a compelling -- where the agency compelled
13 under the imminent hazard authority, that was
14 not for pain management. And I think I
15 testified that that authority was not used, I
16 believe, in Bextra or others.

17 Q. And my question was about pain
18 management.

19 A. So I don't -- I don't --

20 Q. You don't know?

21 A. No. I don't believe that the
22 imminent hazard authority for drug was used to
23 compel withdrawal. And that's really the
24 authority that one has under the act to compel.

1 Q. My point, sir, is that drugs have
2 come off the market because the FDA, working
3 with manufacturers through a process, has
4 determined that they shouldn't remain on the
5 market. And whether you call it voluntary or
6 you call it compelled, that has happened, and
7 it's happened with regard to pain medicines.

8 A. So I'm not prepared -- I haven't
9 done the homework to know exactly the
10 historical reason and back-and-forth, or the --
11 what was in the minds of the individuals at the
12 times they made the decisions on Bextra or --

13 Q. Do you know it's generally true
14 that it happened?

15 A. I'd want to go -- I'd want to go
16 back and review the historical record on
17 exactly why it was done in Bextra.

18 Q. So when you're giving testimony
19 about whether the FDA could or could not have
20 asked for withdrawal of any opioid product, you
21 don't -- you don't know enough, do you?

22 MR. RAFFERTY: Object to the form.

23 A. Are you kidding, ma'am? Are you
24 being --

1 Q. Are you --

2 A. I don't know enough about what,
3 please?

4 Q. Let me ask a different question.

5 Is it your testimony that the FDA
6 should have asked for withdrawal of opioid
7 products?

8 A. I mean, in certain instances it
9 clearly should have. And -- I mean, I think
10 the record shows that, that in certain
11 instances it should have done that.

12 Q. Beyond -- those are instances where
13 it did do that?

14 MR. RAFFERTY: Object to the form.

15 Q. There are certain opioid products
16 that we know have come off the market?

17 A. Yes.

18 Q. I assume you're alluding to those?

19 A. Yes.

20 Q. Aside from those instances where
21 opioid products that were licensed actually
22 came off the market at the behest of FDA, are
23 you -- I want to know, are you saying that
24 there are other opioid products that you --

1 that it's your opinion should have come off the
2 market?

3 A. I think -- in certain instances --
4 I mean, for example, the oxymorphones, the
5 super-fentanyl's that we talked about earlier,
6 there are certain opioids -- if they -- I think
7 the way to probably phrase it, that if they
8 cannot be -- if they cannot be safely -- if
9 they cannot be appropriately and safely used
10 and marketed, I mean, for the intended
11 populations, that their introduction into
12 interstate commerce puts people at risks.

13 Q. Is it your testimony that
14 extended-release single-agent oxycodone
15 products should have come off the market?

16 A. It's a complicated question.

17 Q. No, it's very simple. I want --
18 you're offering opinions in this case.

19 I want to know whether it is your
20 opinion that extended-release oxycodone
21 products should have been removed from the
22 market at any point in time up through today?

23 MR. RAFFERTY: Objection, move to
24 strike the preamble.

1 A. You're asking me specifically
2 oxycodone?

3 Q. Extended-release oxycodone products
4 is what I'm asking about right now.

5 A. Right. So I don't -- I did not
6 favor, in 1994, the removal, I mean, of -- when
7 I was confronted with an opioid, it was a
8 different opioid -- the removal of, for
9 example, the fentanyl patch from the market.

10 Q. Sir, I'm not asking you about
11 fentanyl patch.

12 A. But I mean, I'm just --

13 MR. RAFFERTY: You asked his
14 opinion, and he's giving your opinion.

15 THE WITNESS: And I offered --

16 MS. FREIWALD: No, I didn't ask his
17 opinion on --

18 (Simultaneous speaking.)

19 MR. RAFFERTY: You did.

20 MS. FREIWALD: Troy, I didn't ask
21 his opinion on any subject he wants to
22 talk about. I asked his opinion whether
23 extended-release oxycodone products
24 should have come off the market.

1 A. The -- I am in general -- I took
2 the position back then, in 1994, and I hold it
3 today, that for the risk/benefit equation in
4 cancer, and certainly in some types -- in very
5 limited types of non-cancer pain, right, that
6 the risk/benefit equation, right, would
7 continue justifying that continued marketing.

8 I do think going forward, in the
9 light of the -- the fact that there's now
10 only -- there is one -- there's one randomized
11 controlled clinical trial for a year that shows
12 no -- that does not demonstrate efficacy, and
13 the fact that the agency doesn't have and has
14 admitted that it doesn't have long-term
15 efficacy -- when I said earlier, I think FDA is
16 going along, in the absence of that evidence,
17 you sit there and you think, how can I justify
18 leaving this on the market, right, because
19 there's not long-term evidence for chronic use
20 for extended-release oxycodone. So it's a
21 conundrum.

22 And I think the agency -- certainly
23 when I was at the agency, because you wanted to
24 walk this balance carefully and you don't want

1 to upset the apple cart, all right,
2 that you're -- and it's already on the market,
3 you want to be careful.

4 So I think there is a continued use
5 for cancer. My guess is that that will
6 continue. My sense is, the evidence is not
7 supporting non-cancer use, I mean, as far as
8 the clinical trials.

9 But I mean, I think that that
10 question is still out as far as the evidence.
11 The evidence is not there. And I think
12 eventually the agency, depending on that
13 evidence, is going to have to make a hard call,
14 harder than it's wanted to make.

15 But I think for the time being, if
16 you leave it for cancer and some very limited
17 cases for non-cancer, right, and you limit it
18 to short-term, lowest dose, that would be my
19 opinion today. But I -- but I recognize that
20 I'm going against the traditional standard of
21 having adequate and well-controlled clinical
22 trials because they don't exist.

23 Q. So just the answer to my question
24 simply is, no, you're not going to offer an

1 opinion that the products -- the
2 extended-release oxycodone products should have
3 been completely pulled from the market at some
4 point in time up through today?

5 A. I think I just answered that
6 question.

7 MR. RAFFERTY: Object to the form.

8 Q. Okay. So the answer is, you're not
9 going to give that opinion?

10 MR. RAFFERTY: Object to the form.

11 A. I would give the opinion -- I would
12 give the answer that I gave to you previously.

13 Q. I want this -- I want this -- a
14 simple -- I want to know simply, and then we
15 can talk about where you think the lines are.
16 I'm happy to have that conversation with you
17 later about what you think the correct labeling
18 should be and everything else. And we'll have
19 it, I promise you.

20 But the -- but the simple answer to
21 my question is that you're not going to give an
22 opinion that the products should have at some
23 point in time up through today been completely
24 taken off the market?

1 MR. RAFFERTY: Object to the form,
2 asked and answered.

3 A. I think I answered your question.

4 Q. So that's correct, right?

5 MR. RAFFERTY: Object to the form,
6 asked and answered.

7 A. I believe that --

8 Q. It's a yes or no question.

9 MR. RAFFERTY: It's not a yes or no
10 question.

11 MS. FREIWALD: It's yes or --

12 MR. RAFFERTY: He said it's a
13 complicated answer.

14 MS. FREIWALD: I'm --

15 A. Let me see if I can get it yes or
16 no. Let me just see -- let me just try it one
17 more time. Let me just see the question.

18 I think it would be fair to say
19 that I will not give an opinion that at some
20 point in time up through today, they should be
21 completely taken off the market.

22 But I think I would add into that
23 sentence what I said, right, but I do recognize
24 that, in terms for chronic non-cancer pain,

1 there is -- there is a lack of efficacy. And
2 that gives me pause.

3 Q. Okay. So we'll talk about that
4 later.

5 And if I were to ask you the same
6 question for immediate-release oxycodone
7 product, would the answer also be that you're
8 not going to give an opinion that those
9 products should have been taken off the market?

10 MR. RAFFERTY: Object to the form.

11 A. I'm not going to venture into that
12 area. I don't intend to -- sitting here --
13 again, the legal status of those products are
14 complicated because they're DESI products, and
15 it opens a whole can of worms.

16 So I'm not going to get up on the
17 stand and say, IR products should be off the
18 market. But I think there is a complex answer
19 to that question.

20 Q. And you've never taken the position
21 that hydrocodone products should come off the
22 market?

23 A. I have not.

24 Q. Okay. And that's not going to be

1 an opinion you're offering?

2 A. I'm not taking -- I don't
3 believe -- I mean, again, these are -- these
4 are very powerful -- I mean, if they cannot be
5 used safely, they do not belong on the market,
6 is the answer.

7 Q. Not anything that you ever
8 advocated for while you were Commissioner?

9 A. I dealt with fentanyl when I was
10 Commissioner.

11 Q. Hydrocodone, I said.

12 A. But I'm just telling you what I did
13 at -- did do as Commissioner. I did not do
14 hydrocodone.

15 Q. Okay. Now, in terms of the types
16 of documents that the FDA can ask for
17 pre-approval -- I'm going back to the
18 conversation we were having probably 20 minutes
19 ago or more -- is there any situation that you
20 can think of in your long history with the FDA
21 where the FDA has asked a company if it could
22 see marketing plans, sales forecasts, any other
23 kinds of internal e-mail communications about
24 marketing intentions as part of its approval

1 process?

2 MR. RAFFERTY: Object to the form.

3 A. I'm not aware of the agency doing
4 that, certainly routine.

5 Actually, that's not true. That's
6 not true. I did it.

7 Q. When did you do it?

8 A. I did it in -- I did it in Oralet.
9 I wanted to see the marketing plans. I'm
10 pretty sure I did it in Oralet.

11 Q. So in Oralet, prior to approval?

12 A. Yes.

13 Q. You asked the company for the
14 marketing plans?

15 A. Absolutely.

16 Q. Okay. And why did you do that?

17 A. Because I -- because I was worried
18 that a child would die.

19 Q. I'm not really familiar with
20 Oralet. Can you give me the five-second
21 version of why that --

22 A. Predecessor to Actiq.

23 Q. Okay.

24 A. Intended for use in children

1 preoperatively. Rebranded for use in cancer
2 break-through pain.

3 Q. Okay. And so you asked for
4 marketing plans prior to approval. And did you
5 get them?

6 A. Yeah. I insisted -- it was a -- it
7 was a -- it was a -- I mean, I said I would --
8 unless we could control -- actually, I --
9 actually, I think -- I'm sorry.

10 In reflection, I think what we
11 asked for was a commitment that there be no
12 marketing. There was no promotion.

13 Q. I just want to make sure I
14 understand your testimony.

15 A. Right.

16 Q. Did you ask for marketing plans
17 prior to approval of Oralet?

18 A. We -- I'm pretty sure we asked for
19 documents that would confirm that there would
20 be no promotion.

21 Q. Okay. Do you recall actually
22 seeing or having one of your designees see some
23 type of internal company document? Or was --
24 is that what you saw?

1 A. Yeah, so I -- I mean, I saw there,
2 for example -- I think we'd have to go back and
3 look at the record, for example. It was a
4 ten-hour advisory committee that I was at, and
5 I was insisting that this drug be used in only
6 certain settings and not be widely used.

7 Q. And were you invoking some specific
8 statutory authority in asking for that
9 marketing information prior to drug approval?

10 A. Protection of the public health.

11 Q. What I'm asking -- indulge me if
12 this is a stupid question -- are you -- did you
13 believe that you had authority pursuant to some
14 specific provision of some specific regulation?
15 Or did you just think it was part of kind of a
16 penumbra power that you had in the FDA?

17 A. Fair question. I'm not sure I
18 asked counsel specifically the authority. I
19 felt I had the authority not to approve --
20 to -- the drug was so dangerous that it should
21 not be used unless there was -- it was the
22 predecessor to REMS.

23 Q. Okay.

24 A. I mean, it was -- it was --

1 actually, I'm sorry, that's not correct. I
2 misstated.

3 There was -- there was something
4 called a -- as part of the Accelerated Approval
5 regs, there was the restricted distribution
6 regs. So we did have the authority under the
7 restricted distribution, and that was to
8 anesthesia and no promotion. I believe those
9 regs hold, governed -- they were probably in
10 effect by '94.

11 Q. The gist of what I'm hearing you
12 say, though -- and correct me if I'm wrong --
13 is that you found yourself in a circumstance
14 where you weren't going to get trapped in the
15 minutia of what your authority was if you
16 thought that you needed to ask for something to
17 protect the public interest before a drug was
18 approved. You were going to ask for it and you
19 did.

20 A. You can do that a few times in your
21 life before your counsel will tell you you
22 can't do that, right. I mean, so I'm very
23 respectful.

24 I don't think I was acting

1 extra-statutory or outside of my authority, and
2 no one at that point said it was -- but it
3 was -- so I think I was acting per that.

4 Maybe, you know -- I can't tell you whether
5 my -- whether counsel was -- what they thought
6 at the moment. I just don't remember.

7 But those are the kind of
8 discussions that we would have, exactly the way
9 you and I are talking now. I mean, how
10 explicit is that authority? Is that
11 traditional?

12 And I mean, again, it's not -- the
13 fact that I was so hands-on in Oralet was not
14 traditional, meaning the pre-approval stage.

15 Q. So -- and I'm -- just to be clear,
16 I'm not in any way suggesting that you were
17 over your authority on that. I'm simply trying
18 to understand that, when faced with the
19 situation where you thought you needed to do
20 something to protect the public health, as
21 Commissioner of the FDA, you did it if you felt
22 that you had a reasonable basis for doing so.

23 A. Yeah. I had to go to law school in
24 order to have that confidence. Not everybody

1 has that --

2 Q. Okay.

3 A. -- confidence to do that.

4 Q. It's something Commissioners of FDA
5 can do?

6 A. They have different philosophies,
7 and they have different styles, and there are
8 certain Commissioners who would never make a
9 decision without having counsel sign off on it.

10 I mean, I didn't feel that that
11 was -- I could -- I would discuss it with
12 counsel legally and I'd be able to make my own
13 determination, being respectful of their
14 opinions.

15 Q. Okay. But from Commissioner to
16 Commissioner, there are things that the person
17 in charge can decide to do. It may not be a
18 hundred percent clear what the authority comes
19 from, but it's a broad -- the broad mandate to
20 protect the public health can allow you to do
21 the kinds of things you did in Oralet?

22 A. That is a -- you know, if you --
23 you can bring in 12 members of the food and
24 drug bar, and they can spend the next four

1 hours discussing that subject. I can tell you
2 most -- it's not the way the agency
3 traditionally works, right. You can do that
4 rarely, right.

5 Again, we were, in essence,
6 invoking risk maps or REMS before there were
7 risk maps or REMS. And we put those things,
8 and the product was not a success.

9 Q. Okay. Because you thought it was
10 important. You did what you did because --

11 A. It was in the case of a pediatric
12 situation. But I think other Commissioners
13 would not feel that that would be the right
14 thing to do.

15 Q. Okay. So reasonable Commissioners
16 could disagree about what the right thing to do
17 is on a case-by-case basis?

18 A. Correct.

19 Q. Okay. And are there other examples
20 where you have asked for or obtained internal
21 company documents or you know that colleagues
22 of yours have as a condition to approval or
23 post-approval of a drug?

24 A. Certainly I remember there were

1 certain issues involving -- actually, the one
2 that comes to mind is a device, but it was
3 probably also classified as a drug at certain
4 times where those kind of e-mails and
5 back-and-forth post-approval certainly did come
6 to play.

7 Q. You mean the agency asked for --

8 A. The agency got hold of, and it
9 influenced the agency's decision-making.

10 Q. Okay. Are you aware of any
11 situation for any of the manufacturers about
12 you have -- about whom you have opinions where
13 the FDA requested internal company documents
14 like you're talking about and they were
15 refused?

16 A. I'd have to think about the answer
17 to that question. I mean, the Roth study
18 doesn't quite -- I mean, would that be in that
19 category?

20 Q. You tell me.

21 A. The -- when the meta-analysis from
22 your client, is that -- is that in that
23 category?

24 Q. So I'm talking about what we've

1 been talking about up until now, which would be
2 marketing plans, strategic documents, internal
3 e-mails about business intentions or goals. I
4 think you mentioned return-on-investment
5 analyses earlier in the deposition.

6 Right now I'm not talking about any
7 scientific studies.

8 A. FDA --

9 Q. My question -- specifically my
10 question --

11 A. I'm not aware of any, sitting here
12 right now.

13 Q. Okay. I also want to be clear that
14 we have the same understanding about the rules
15 around promotion. So is it your testimony that
16 a company can promote a product inconsistent
17 with its FDA-approved label?

18 A. I wouldn't phrase it that way, no.

19 Q. Okay. Is it your testimony that a
20 company is required to promote its product
21 consistent with its FDA-approved label?

22 A. Again, I think generally, yes, but
23 the -- but the correct answer -- I mean, I
24 think the answer is "yes" to that, but -- the

1 statutory answer, but, again, that -- we
2 discussed this earlier. It would be based
3 on -- the real issue is, you have to base your
4 promotion on substantial evidence of adequate
5 and well-controlled clinical trials. And the
6 label isn't a surrogate, but if the label
7 doesn't contain it or you have adequate and
8 well-controlled clinical trials, that's what
9 governs.

10 Q. Is there any scenario you are aware
11 of where the FDA has said to a company, we're
12 going to approve your product and give you a
13 label for the product, but we don't think you
14 have adequate and well-controlled trials?

15 MR. RAFFERTY: Object to the form.

16 A. Where the FDA said that?

17 Q. Yeah.

18 A. Well, I mean -- I mean, it said it
19 where? I don't mean to be difficult here.

20 Q. Well --

21 A. But clearly you mean, in this
22 instance, this drug -- your client's drug, I
23 mean, is approved and -- for, in essence,
24 chronic pain. And the FDA has said, there's

1 not adequate and well-controlled trials
2 demonstrating efficacy for chronic pain. So
3 that's the conundrum we're in.

4 Q. Well, I --

5 A. The FDA has said that, but it
6 still -- it hasn't withdrawn the product.

7 Q. Well, I'm going to -- I'm going to
8 probably differ with you on exactly what FDA
9 has said on that subject.

10 But can we -- can we agree that it
11 is -- the reason that the label is -- I forget
12 what you said -- a proxy or a surrogate for
13 adequate, well-controlled studies is because
14 you're not going to get a label if you don't
15 have adequate and well-controlled studies?

16 MR. RAFFERTY: Object to the form,
17 move to strike the preamble.

18 A. Well, that's wrong. I mean, there
19 are not -- there are numerous statements. I'm
20 happy to take them out -- I mean, I've spoken
21 to Califf, I've spoken to Janet. There is no
22 one who is going to sit and testify and say
23 there -- certainly, I mean, that I'm aware of
24 from FDA that's going to testify that there are

1 adequate and well-controlled clinical trials to
2 support the long-term efficacy for chronic
3 pain. That doesn't exist.

4 Q. To support the label for the
5 product?

6 A. Well, so the label for the product
7 as currently written includes chronic use,
8 right. That changed over time, I think, right.
9 I mean, what, in 2012, the label went from
10 extended period of time to chronic use. And
11 there are not adequate and well-controlled
12 clinical trials to support that label.

13 And I don't think there's any
14 disagreement on that. Certainly if you talk to
15 Dr. Woodcock or Dr. Califf, and certainly the
16 one trial we have, right, the space trial shows
17 no efficacy. So that's the problem.

18 Q. Sir, most drugs that are on the
19 market don't have randomized, controlled
20 clinical trials to support use for years and
21 years, most drugs, at the time they're
22 approved, correct?

23 MR. RAFFERTY: Object to the form.

24 A. But most drugs have the studies to

1 prove what the intended use is.

2 Q. Well, no. Most drugs have studies
3 in a limited population for months or maybe a
4 year or maybe a year and a half, but then
5 people can be on those drugs for five years,
6 ten years, a lifetime.

7 MR. RAFFERTY: Object to the form.

8 A. That's fair. And -- but as you
9 said, that at least you have a year of data or
10 two years of data to support efficacy. You
11 don't have that here.

12 Q. Actually, you do have multiple
13 trials that go out years. They're not all
14 double-blind, but you do have trials that go
15 out years.

16 MR. RAFFERTY: Object to the form.

17 A. You don't have adequate and
18 well-controlled trials. Certainly on approval
19 and even to this day, you don't have adequate
20 and well-controlled clinical trials as defined
21 by the act to support the label.

22 Q. So the label should have said, you
23 can be on this product for 6 months or 12
24 months?

1 MR. RAFFERTY: Object to form.

2 Q. The FDA could have said that.

3 A. So the label said originally a few
4 days. You had controlled trials for 14 days.

5 Q. Well, the FDA asked for the change
6 of -- to an extended period of time.

7 A. So as -- the FDA asked first for a
8 few days because it wanted to match, I believe,
9 the -- some of the prior pain medicines, and it
10 was trying to make it consistent.

11 FDA tried to narrow it for an
12 extended period of time, and that goes back to
13 the discussion we had earlier.

14 Q. Okay. So let me ask the question
15 this way. Are you aware of any regulation,
16 statute, guidance that says the indication for
17 the drug may be broader than what the company
18 is allowed to promote the drug for?

19 MR. RAFFERTY: Object to the form.

20 A. I apologize, I don't understand
21 that question.

22 Q. Okay. Is there any -- I probably
23 asked it badly, so I'll try again.

24 Is there any regulation or statute

1 or guidance from the agency or other official
2 writing -- I'm trying to cover the universe on
3 official writings -- that would tell a
4 manufacturer that gets an approval for a drug
5 with a particular indication that,
6 notwithstanding the approved indication, its
7 promotion of the drug has to be more
8 restricted?

9 A. Well, FDA did that -- FDA did that,
10 in essence, here.

11 Q. I'm asking as a general rule-making
12 document.

13 A. When I would -- as a general
14 rule-making document.

15 As a general rule-making document,
16 you have to have adequate and well-controlled
17 clinical trials. That's the regulation. And
18 that's the regulation for which you can
19 promote.

20 Here --

21 Q. It's also the regulation for which
22 you get approval, right?

23 A. Sure.

24 Q. Okay.

1 A. Okay. Here, those studies didn't
2 exist. And, I mean, in part you're dealing --
3 because this was bioequivalence, and you go
4 back to the DESI review, and that adds
5 complexity.

6 But here, 2001, both -- I mean,
7 1995, 1996, Dr. Wright saying, not step two,
8 not the one to start with. 2001 we discussed,
9 restricting -- trying to -- Jenkins trying to
10 narrow that. The language admittedly was
11 fuzzy.

12 Q. I think you're misunderstanding my
13 question.

14 A. I'm sorry.

15 Q. That's fine. Let me -- I'm going
16 to try to break it up --

17 A. Sure.

18 Q. -- into little pieces and see if
19 that's easier.

20 So first of all, just -- if one
21 were to go and say, I want to know generally
22 how the rules work with FDA and try to look at
23 the appropriate regulations and guidance
24 documents, would you find any regulation or

1 guidance document that says a manufacturer
2 should market its product more narrowly than
3 its indicated use?

4 A. I don't know if there's a -- I
5 don't know if there is a rule, I doubt it,
6 that's -- because it would probably be
7 inappropriate -- I mean, follow what FDA is
8 telling you. I don't know if there's a rule
9 that says that.

10 Q. Okay. So then the next step is, is
11 there any reason -- if FDA wants to impose some
12 marketing restriction on a document -- on a --
13 on a product -- let me strike that and ask it
14 more cleanly.

15 If FDA wants to impose a
16 restriction on the marketing of a product so
17 that the marketing is more limited than the
18 indication might allow, does it have the
19 authority to do that?

20 A. Once it's on the market, as you see
21 in those minutes and you see FDA, in essence,
22 threatening -- I don't think that's an
23 overstatement -- but FDA -- the authority FDA
24 had, because it threatened and it said, if you

1 don't bring this under control, if you don't do
2 that, we're going to be forced to work towards
3 getting your drug off the market.

4 Q. Okay. So good. That's
5 post-approval?

6 A. That's post-approval.

7 Q. So post-approval, if a company is
8 marketing a product, even if technically within
9 the boundaries of its indication, but beyond
10 what the FDA thinks is appropriate, the FDA can
11 say, we're going to -- we're not -- we're not
12 okay with your marketing, and if you don't
13 modify, you may not have any marketing at all?

14 A. Well, they --

15 Q. May not have any product at all?

16 A. -- they said that at a certain
17 point. There was a pretty strong statement,
18 right, probably out of frustration, right.

19 Q. Okay.

20 A. But it could probably also send
21 DDMAC letters and go through the DDMAC process.

22 But understand, you have in your
23 question -- the way you set this up is sort
24 of -- I'm not sure I fully agree because you

1 said, assume that it's within the indication,
2 but for which FDA says it has to be narrower,
3 so then FDA obviously doesn't think it's within
4 that indication.

5 And I think that's the rub here.

6 Q. So in 2001 -- I think this is what
7 you're alluding to -- in communications with
8 the FDA with regard to OxyContin, the FDA said,
9 we're going to make changes to the label, and
10 we're looking carefully at the marketing
11 practices, and if we can't get alignment, we
12 have the authority to go as far as removing the
13 product from the market, correct?

14 A. I'm not sure they said, we're
15 looking at the marketing practices.

16 I think what FDA was looking at was
17 abuse that was going on. I think that's what
18 the letter said at the time.

19 Q. So it was trying to get the abuse
20 under control, not necessarily tied to the
21 marketing?

22 A. We'd have to go -- I mean, again,
23 let's pull the letters when we come back.

24 Q. We'll do that.

1 A. All right.

2 Q. Okay. So but one -- but your
3 testimony, if I hear you correctly, is that the
4 FDA has authority to restrict marketing if it
5 has concerns about safety issues in the
6 post-marketing period.

7 A. So maybe --

8 MR. RAFFERTY: Object to the form.

9 A. If there is marketing that
10 understates the risk or overstates the benefit,
11 right, or broadens the indication, that's when
12 FDA has specific authority. So it's not just
13 when it has, quote, safety concerns.

14 Now, you can get into a 505
15 argument, but it's usually understatement of
16 risk, overstatement of benefits, lack of fair
17 balance, broadening. That tends to be the lens
18 through which the FDA looks at marketing.

19 Q. Okay. And it has various tools --
20 and again, I'm going to tick them off, so don't
21 worry that I'm not getting everything this
22 time. But it can engage in dialogue with the
23 company and try to reach some general
24 understanding?

1 A. Correct.

2 Q. Okay. It can issue what is
3 referred to as an untitled letter with regard
4 to specific marketing activity, correct?

5 A. It can send a letter, yes.

6 Q. Okay. So we refer to an untitled
7 letter as kind of a low-level complaint?

8 A. Yeah. The different letters have
9 different titling standards at different points
10 in time in FDA's history.

11 Q. Okay. And can we agree that a
12 letter that doesn't have a warning moniker at
13 the top is colloquially or in the industry
14 referred to as an untitled letter, and that's
15 considered kind of the first step in written
16 communication that a company could receive?

17 A. As a general rule, you're probably
18 within the ballpark, but I would look at the
19 last paragraph more than the title --

20 Q. Okay.

21 A. -- and see what FDA is saying you
22 need to do because that will tell you whether
23 they're enforcing it or not.

24 Q. Okay. So there are untitled

1 letters and there are untitled letters.

2 A. Fair point.

3 Q. Fair point?

4 A. Fair point.

5 Q. And some are more strongly worded
6 than others?

7 A. Fair point.

8 Q. And some carry more threat than
9 others?

10 A. More consequence.

11 Q. And -- but it's a tool that FDA
12 has?

13 A. Yes, ma'am.

14 Q. And another tool that FDA has is
15 warning letters?

16 A. Correct.

17 Q. Which is another written letter to
18 a company, but this time it says, warning,
19 usually in bold black letters at the top, and
20 it's a way of FDA communicating, we're really
21 super-serious about our concerns here.

22 MR. RAFFERTY: Object to the form.

23 A. Super-serious -- yes, I think
24 that's fair.

1 Q. And it will continue to engage in
2 dialogue with the company about its concerns,
3 correct?

4 A. That's fair.

5 Q. Okay. And is it also fair that FDA
6 may send those letters based on FDA's -- I
7 think you used this term -- net impression of
8 what the promotional materials are saying?

9 A. No. What I think I said is, FDA
10 basically -- this peek-a-boo.

11 Q. No. In your written report. I'm
12 pretty sure --

13 A. Maybe. Let's see if there's net
14 impression. I don't remember, but I'm not
15 saying I didn't. But let me see if I used the
16 word "net impression." Go ahead.

17 Q. So what I'm trying to convey --

18 A. Just looking...

19 Q. -- is, the way FDA will work when
20 it complains about promotional activities is it
21 will have a view that something has the
22 potential to be misunderstood or is unfair or
23 misleading in some way?

24 A. I just want to -- so this is

1 important. The net impression goes to the
2 presentation of risk impression and uses
3 whether the net impression, as a whole with
4 regard to safety information, minimizes.

5 But I don't think that's what your
6 question was. When FDA is making these
7 decisions in these letters, right, it has to
8 have specific conduct certainly in a warning
9 letter or an enforcement letter as opposed to
10 maybe a pre-launch letter, right, that there
11 are specific violations.

12 Q. Okay. But those specific
13 violations could be something like, we saw a
14 sales aid. We think it conveys an impression
15 that is false and misleading because of how the
16 prominence of the risk information, the way the
17 people may be smiling or not smiling. There's
18 all kinds of things that the FDA considers.

19 A. I think that's well said. I mean,
20 if you -- if you give an impression that you
21 have improved functionality from a drug and
22 there's no evidence of improved functionality,
23 right, and somebody is sitting there working,
24 the FDA would say, you have to look at the

1 piece in its totality. I think that's what you
2 mean by "net impression."

3 Q. Okay.

4 A. Or what's meant by "net
5 impression."

6 Q. I think that's a better way of
7 saying it.

8 So the FDA has an impression of the
9 piece based on its totality. It is, though
10 admittedly, subjective, correct? In many
11 situations it's not like -- it's not as if the
12 FDA has gone out and done a poll and proved
13 that everybody who looks at this piece is going
14 to think that it's misleading.

15 A. So you're --

16 MR. RAFFERTY: Object to the form.

17 A. You're correct, Counselor, and
18 that's why it becomes so difficult. Because if
19 you're dealing in a post-approval situation and
20 you want to -- and you have to -- and the
21 manufacturer is fighting you, you would have to
22 do exactly like what you said in court. You'd
23 have to do -- and I've been in this situation
24 where I'd have to do consumer surveys to say --

1 what are these -- what's the net impression?

2 If I'm going to say, this piece
3 misbrands it, I'm going to say, I need that
4 consumer survey.

5 So it can't be subjective. You try
6 to make it as objective as you can.

7 Q. Yeah. But the reality is that no
8 company wants to go to court with the FDA over
9 whether they can have a fisherman in their ad
10 or somebody skiing or something like that.
11 Most of the time, the company is either going
12 to make the change that the FDA wants or
13 they're going to engage in dialogue and say, we
14 don't think this is what it was supposed to
15 convey, and there will be -- either the FDA
16 will agree or they won't agree.

17 MR. RAFFERTY: Object to the form.

18 Q. And the ad will either get changed
19 or modified in part or not.

20 MR. RAFFERTY: Same objection.

21 A. If that were the case, FDA wouldn't
22 need a general counsel's office.

23 I mean, these things -- in many
24 instances you're correct, Counselor.

1 Q. Okay.

2 A. I'm not distinguishing -- but there
3 are instances where that -- you see certain ads
4 on TV that you wonder how they can be on TV
5 still. And it's not that -- not all companies
6 act the same.

7 Q. But that actually happened here,
8 for example. So there were some ads that my
9 client had that the FDA didn't like, and the
10 company said, we'll make the change.

11 And then there were some ads and --
12 do you remember that?

13 A. Yeah -- well, there were certain
14 corrective ads and there was a whole history.

15 Q. I'm not talking about corrective
16 ads. I'm just talking about there were a
17 couple of ads in the 2002 time period that the
18 FDA thought were not appropriate in some way.
19 They wrote the company.

20 The company said, we don't
21 necessarily agree with you, but we'll make the
22 change.

23 Do you remember that?

24 A. I mean, yes.

1 Q. Okay. And that happens?

2 A. Again, to your point, right,
3 because that's what FDA can -- FDA is only as
4 good as what it can see. It's playing
5 peek-a-boo, in essence.

6 Q. Okay. We'll get back to that in a
7 minute --

8 MR. RAFFERTY: Hope, when you --
9 Hope, when you get to a point --

10 MS. FREIWALD: I'm going to finish
11 out this line, and then I'm happy to
12 take a break.

13 MR. RAFFERTY: Okay.

14 Q. And then there were some situations
15 where the FDA said -- just speaking of my
16 company, my client -- we think these ads are
17 not appropriate in various ways, and the
18 company disagreed and wrote to FDA, and FDA
19 said, no, we still think we're right and you're
20 wrong.

21 And ultimately the company did what
22 FDA wanted, correct?

23 A. In certain instances that -- in
24 certain instances, again, I don't disagree with

1 that.

2 Q. Okay. And that's -- that way of
3 operating is not unique to my client, to
4 Purdue; that's something that happens with many
5 companies. They may receive untitled or
6 warning letters, and there can be disagreement,
7 but in the overwhelming majority of cases, the
8 company finds a way to do what the FDA wants.

9 MR. RAFFERTY: Object to the form.

10 A. No. If the company were doing what
11 FDA wants, your company wouldn't have done --
12 you look at the call notes.

13 Q. They make the modification that the
14 FDA -- with regard to the issues raised in the
15 letters that the FDA sends, most companies will
16 make the modifications that FDA wants because
17 they're not going to litigate it.

18 MR. RAFFERTY: Object to the form.

19 A. When you say "what FDA wants," if
20 FDA catches the company on a specific
21 violation, that's true.

22 But look at -- look at the way
23 your -- no --

24 Q. I'm just asking about --

1 A. What FDA wants, you said. But if
2 you look, for example, at all the
3 representations that your client made, I mean,
4 they are -- I mean, when you read those --

5 Q. We'll talk about those, I promise
6 we will.

7 A. But I say -- but let me finish my
8 answer, please, just for a second.

9 When you look at the
10 representations that were made by your company
11 to doctors, there is no way that's what FDA
12 wanted.

13 Q. Okay. I'm just talking about, when
14 there is a letter sent with regard to
15 particular conduct or particular marketing
16 materials, the overwhelming majority of
17 instances there is a change on the -- the
18 company makes to meet what the FDA is asking
19 for.

20 A. You're correct. When you get
21 pulled over by the policeman for speeding, you
22 will usually comply, right.

23 Q. Okay.

24 A. But that doesn't mean you're not

1 going to stop speeding and -- so again, if you
2 get called out in that letter for that specific
3 here, right. But that was the tip of the
4 iceberg.

5 Q. Okay. And the FDA will usually say
6 in those communications, these principles that
7 we're articulating, whatever it -- applying not
8 just to this ad but they apply to other ads
9 going forward?

10 A. Well, it's not only -- you talk --
11 it should apply to promotion.

12 Q. To any promotion?

13 A. And not just any, because there's a
14 distinction there.

15 Q. Fine. Fine.

16 A. You're -- we're dealing with
17 sophisticated companies. I mean, everyone
18 knows that they're supposed to be -- those
19 principles that we've talked about --

20 Q. Right.

21 A. -- should be adhered to. Don't
22 minimize risk, don't overstate the benefits. I
23 mean, that's basic stuff.

24 Q. Right. But, generally speaking,

1 if, for example, the FDA takes issue with how
2 information is presented in a particular
3 marketing piece, the company may say, you know
4 what, we really didn't think this was an issue.
5 We really thought that we showed the fair
6 balance of benefit and risk, but FDA, you
7 don't. Okay. It will get changed.

8 And the FDA will say in that
9 situation, and by the way, this applies going
10 forward, correct?

11 MR. RAFFERTY: Object to form.

12 A. Yeah --

13 Q. I mean --

14 A. -- I think the best answer that was
15 I think ever given I think was given a little
16 while ago on that by your client, I think, who
17 summed it up -- I think Kathe Sackler,
18 Dr. Sackler, summed it up when on -- she said,
19 is it the marketing side of the house that's
20 talking or the scientific side of the house
21 that's talking?

22 Q. Sir -- sir, I'm not asking a
23 question that has anything to do with that.

24 I'm simply asking, FDA's directives

1 are always -- that the principles that they may
2 articulate when they look at a marketing piece
3 and take an issue, they expect the companies to
4 then apply those same principles to other
5 promotional pieces going forward?

6 A. Promotional pieces and conduct.

7 Q. Okay. And in fact, companies will
8 look at what other -- strike that.

9 So untitled letters, warning
10 letters, those are tools the FDA has. And
11 there are cases where the FDA also has other
12 types of enforcement authority, correct?

13 A. Yes.

14 Q. Okay. And it uses those -- that
15 enforcement authority from time to time if it's
16 not happy with a company's promotional
17 practices.

18 A. "Happy" is probably not quite the
19 word, but yes.

20 Q. If it -- if it feels that the
21 promotional practices are not -- are violative?

22 A. Fair to say.

23 Q. Okay. And the FDA has used over
24 the years the full range of its enforcement

1 capabilities in situations where it has deemed
2 it appropriate to do so?

3 A. I don't remember -- correct me if
4 I'm wrong -- that they ever withdraw -- I'm
5 asking this rhetorically because I'm trying to
6 think, has FDA ever withdrawn a drug because of
7 violative marketing? I'm not sure if the FDA
8 has used the full range of tools.

9 So I'd have to go back and think.
10 I can't think of that.

11 Q. It certainly has used other types
12 of enforcement.

13 A. Yeah, but I don't think it's used
14 the full ranges of tools.

15 Q. Okay. And marketing restrictions
16 can be part of a risk map plan or today a REMS,
17 correct?

18 A. We'd have to pull the statutory
19 authority, whether it's exactly phrased the way
20 you're phrasing it.

21 Q. But generally that's right?

22 A. I'd want to review legally -- I
23 mean, I don't -- let me look at that before I
24 answer that specifically.

1 Q. Okay. Do you agree with me that
2 generally, REMS programs, since 2007, have
3 allowed the agency to come up with a range of
4 ways in which it can limit activities around a
5 drug or require additional dissemination of
6 risk information around a drug?

7 A. No, I don't agree. I think -- I
8 think the REMS has been -- I think everybody
9 would agree -- and in my conversations with
10 people at FDA and some of the -- I think REMS
11 has been pretty ineffective here.

12 Q. I didn't ask about effectiveness.
13 I just asked whether the REMS programs give the
14 FDA authority to require -- to limit -- impose
15 limits on products or classes of products, or
16 to require additional risk information be
17 disseminated about those products?

18 A. Yeah, I don't think -- I'd want to
19 go back and just look at the regs because I
20 think the regs and the reality don't give the
21 FDA -- look, for example, just even a
22 physician -- a patient -- the kind of
23 registries that we're talking about, FDA
24 doesn't have the capability.

1 The reason why a lot of this was
2 voluntary was, FDA didn't have the capability
3 to do this. So it had to do this in this --
4 sort of on a voluntary basis and turned it over
5 to the manufacturer because it really didn't --
6 maybe -- and I'd -- and I'd want to go back and
7 think about this.

8 Maybe theoretically you can argue
9 it has the authority, but in reality, FDA
10 really was -- I mean, I think feeling very
11 impotent on being able to really put in place
12 controls to change back the practice of
13 medicine to where it should be.

14 Q. I thought you told me that you
15 weren't going to testify as to what anybody
16 felt.

17 MR. RAFFERTY: Object to the form.

18 A. I'm answering your question --

19 Q. I think you --

20 A. -- the best I can.

21 Q. Well, you just said that FDA was
22 feeling very impotent. I thought we agreed we
23 weren't going to testify to --

24 MR. RAFFERTY: Object to form.

1 A. That's fair. I think I can tell
2 you that FDA has stated -- I mean, if you look
3 at the facts -- that FDA doesn't have the
4 resources to conduct, for example, the kind
5 of -- the kinds of real REMS that you would
6 need to change the perception of opioids in
7 this country. I think it has some tools, but I
8 don't think it has -- I mean, and you see those
9 limitations in how FDA -- what FDA imposed. It
10 didn't mandate the kinds of registries of
11 doctors, et cetera.

12 Q. Okay. I mean, we'll talk --

13 MR. RAFFERTY: We need to take a
14 break for lunch soon.

15 MS. FREIWALD: Yeah, I just want to
16 finish out this one question and then --

17 MR. RAFFERTY: It's been -- okay.

18 Q. We'll talk about the specifics of
19 the REMS later, I promise, and what was
20 effective or you may -- you may have issue
21 with.

22 But just at a high level, REMS
23 programs can require companies to disseminate
24 additional risk information, correct?

1 A. Fair.

2 Q. They can require companies to
3 disseminate additional information about safe
4 use, correct?

5 A. Yes.

6 Q. And they can impose limitations on
7 marketing or promotion.

8 A. Consistent with certain other
9 limitations, you have a whole First
10 Amendment -- I wouldn't want to answer that.
11 Yeah.

12 But as you saw, FDA may have
13 certain authority, but you still have
14 misleading information under the REMS.

15 Q. Well, we'll talk about that later.
16 But just what the REMS allows them to do.

17 And it also allows for tracking and
18 monitoring and other kinds of programs?

19 A. Yeah. Again, but recognize the
20 limitation -- FDA doesn't have the limit --
21 doesn't have the -- the real authority to do
22 that is beyond FDA's scope.

23 Q. Okay. But conceptually, that's --
24 those are elements of a potential REMS program.

1 A. We can look -- the regs speak for
2 the regs.

3 MS. FREIWALD: Okay. Why don't we
4 take a break.

5 VIDEO OPERATOR: 1:12. We are off
6 the video record.

7 (Recess from 1:12 p.m. until
8 2:14 p.m.)

9 VIDEO OPERATOR: 2:14, we are on
10 the video record.

11 BY MS. FREIWALD:

12 Q. Doctor, I'm going to change topics
13 for a minute. Can I ask you to pull out your
14 CV, which is an exhibit to your report.

15 A. Sure.

16 And I -- Counsel, I just want to
17 make one sort of clarification at some point
18 just for a minute --

19 Q. Sure.

20 A. -- to a prior -- but no rush.

21 Q. Yeah, we'll get to it later, if
22 that's okay.

23 A. Perfect.

24 Q. All right. So I just -- they are

1 numbered. Page 11, under Lectureships.

2 A. Yes.

3 Q. So you gave a Beth and Richard
4 Sackler lecture at the University of
5 Pennsylvania. When was that, sir?

6 A. You know, I went to check, try to
7 find that out. My guess is -- in the late
8 1990s is my best --

9 Q. Okay.

10 A. -- recollection, but I could be
11 off. I couldn't find anything on the web page.

12 Q. So does lectureships mean something
13 different from lectures?

14 A. Yeah. So a lectureship -- the
15 University -- University of Pennsylvania got an
16 endowed -- I assume an endowed gift, and
17 University of Pennsylvania invited me to give
18 at the University of Pennsylvania a lecture,
19 which I did, which was named this.

20 Q. And do you remember what the topic
21 of the lecture was?

22 A. I could be pretty sure -- I could
23 be 99 percent sure.

24 Q. What's your 99 percent sure?

1 A. It was about tobacco.

2 Q. Okay. And so this is an
3 educational program that was endowed by Beth
4 and Richard Sackler?

5 A. Actually, I don't -- Beth is the
6 graduate.

7 Q. Okay. This is the same Sackler
8 family as Purdue, correct?

9 A. Yes, I believe -- yes --

10 Q. Okay.

11 A. -- I have every reason to believe
12 it was.

13 Q. Okay. And so the Sacklers endowed
14 an educational lectureship, as others do. We
15 have the Weinberg Symposium lecture, the Thomas
16 Ferguson lecture, the George E. Altman lecture.

17 A. Most of whom, I have no idea who
18 they are.

19 Q. Okay. And you were given the
20 opportunity to talk about a topic that was of
21 interest to you and of interest to the
22 audience?

23 A. Maybe not exactly that way. But,
24 you know, Mr. Sackler, I think, graduated, had

1 an interest in some of the social sciences.

2 We'd have to go back and see, if we
3 could pull out the letter, whether it was
4 asking me to talk about something in the social
5 science that was of interest to -- I don't know
6 what the letter from Penn stated. I apologize.

7 Q. The point is, you thought it was an
8 educationally valuable thing to do?

9 A. At the University of Pennsylvania,
10 I gave a lectureship.

11 Q. Okay.

12 A. Yes, I have no problems with that.

13 Q. And you -- and you had free reign
14 in the content of what you talked about?

15 A. Pennsylvania did not put any --
16 University of Pennsylvania did not put any
17 restrictions. This was not promotion. This
18 was not drug-related at all.

19 Q. Right.

20 And you didn't have any problem
21 with the fact that it was endowed by people who
22 owned a pharmaceutical company. They weren't
23 controlling your content, right?

24 A. She -- I don't know what her role

1 is. I think she -- I mean, I don't, you
2 know --

3 Q. The fact that it was a Sackler
4 lecture didn't make it a bad thing to do, in
5 your mind, did it?

6 A. Well, I think there's some issues
7 whether I should keep it on. I hear she's
8 divorced from Richard. I can make a -- I
9 wanted to leave it on here because it's been on
10 here, and I didn't want to take it off to hide
11 anything. So I left it on here.

12 We can decide. Maybe as group, we
13 can take a vote whether I take it off or not.
14 I don't know.

15 Q. The point is, this is something you
16 actually did --

17 A. I did.

18 Q. -- you were willing to do.

19 A. Yes, I did. The University of
20 Pennsylvania, it was -- it was the University
21 of -- this was a university-wide lecture. I
22 was able to talk on tobacco.

23 Q. And you didn't feel like you were
24 corrupted by the -- by the fact that it came

1 through a Sackler-funded program?

2 A. No, at the time, I did not.

3 Q. Okay.

4 A. I mean, I -- absolutely, I had --
5 at the time, I did not feel that way, if we're
6 talking about subjective feelings.

7 Q. Okay. And then you also have on
8 your CV reference to FleishmanHillard on
9 page 8, corporate board and advisory --

10 A. They had a global advisory board.

11 Q. Okay. They're a PR firm, right?

12 A. They are an international PR firm.

13 Q. And they do PR in the
14 pharmaceutical space?

15 A. Among others, yes.

16 Q. Okay. They -- among other things,
17 they advise companies with regard to promotion
18 of pharmaceutical products?

19 A. Yeah. Generally, I'm not -- well,
20 that probably is correct, yes.

21 Q. Okay. And what -- what has your
22 role been for the last decade-plus with
23 FleishmanHillard?

24 A. So where is it --

1 Q. It was --

2 A. You know, I --

3 Q. -- 2003 to 2014.

4 A. I'm blocking on Paul's last name.

5 This was really a very informal -- where Paul
6 would sometimes call, sometimes ask questions,
7 those kinds of things.

8 Q. So is Paul, Paul Fleishman or
9 Paul --

10 A. No.

11 Q. -- Hillard, or is there is
12 different Paul?

13 A. No. There's a different Paul. And
14 I apologize. I'm blocking.

15 Q. Okay.

16 A. My age is showing.

17 Q. So --

18 A. He was running the D.C. office.
19 And this was Panetta, a number of officials.

20 Q. So you tell me if I'm
21 misunderstanding here, but I'm assuming that
22 FleishmanHillard engaged you at various points
23 in time between 2003 and 2014 because of your
24 FDA expertise to help them with clients that

1 they had who interfaced with the FDA or who
2 might have products that are regulated by the
3 FDA.

4 A. Actually, I -- no, I don't think I
5 got into any client work with FleishmanHillard
6 that I'm aware of.

7 Q. What did -- what types of work did
8 you do?

9 A. For Paul -- I mean, I would -- I
10 mean, it was general, very broad kinds of
11 questions.

12 I guess, there was one academic
13 institution -- I'm not sure whether that was a
14 successor to Fleishman or not -- that Paul
15 asked me to come to give a speech on clinical
16 evidence. It was those kinds of things.

17 Q. Okay. Do you know how much money
18 you made working with FleishmanHillard?

19 A. I have no idea. I can't say.

20 Q. Would it be more than \$100,000?

21 A. It's possible. I just -- I have no
22 recollection. Over the -- over the collective
23 time period, it's possible.

24 Q. More than two hundred?

1 A. I have no idea. I could not
2 answer.

3 Q. Could it be more than a million?

4 A. Probably not, no. But I -- but
5 again, I don't have -- I don't think that's the
6 case.

7 Q. Okay. Do you -- and do you know
8 how many days a year or whatever you might have
9 devoted?

10 A. It was very few. It was really
11 when Paul called and asked.

12 Q. Could it be as much as a half a
13 million dollars you made with FleishmanHillard
14 over this time period?

15 A. I told you I don't know, and I
16 just -- I don't know.

17 Q. Not even a ballpark?

18 A. I apologize. I have no idea.

19 Q. Okay. Did you talk to
20 FleishmanHillard about any of their work for
21 any pharmaceutical company?

22 A. No, not that I -- not that I
23 remember. I may have talked about DTC at a
24 little point, but not for any client or

1 anything else like that. But it was -- it was
2 at the 30,000-foot level about DTC. That's the
3 most I remember.

4 Q. Why would a PR firm want your help?

5 MR. RAFFERTY: Object to the form.

6 A. You'd have to ask them why they
7 would want my help. The same reason they would
8 want, you know, Leon Panetta and others. This
9 has to do something with --

10 Q. You just lost your mic, sir.

11 A. Oh, I'm sorry.

12 Fleishman has -- and, again, their
13 motivation is --

14 Q. Why did you understand that they
15 wanted your help? I'll rephrase it to take out
16 their motivation.

17 A. I think he just wanted advice on
18 certain -- he wanted the ability to ask
19 questions, if he had those questions.

20 THE WITNESS: I'm sorry. Am I not?

21 VIDEO OPERATOR: You pulled it off
22 again.

23 THE WITNESS: I'm sorry.

24 A. I think he just wanted the ability

1 to ask certain questions and have -- to take
2 advantage, if he ever needed it. I think
3 that's what they wanted.

4 Q. Okay. And again, you could have
5 made as much as a hundred -- as much as
6 \$500,000 working for them, and that didn't give
7 you a problem, right?

8 MR. RAFFERTY: Object to the form.

9 A. Working for -- for doing on -- this
10 kind of advisory work, I -- I had no problems
11 working for Paul. I always found -- I didn't
12 see anything wrong there, no.

13 Q. Okay. You thought they were a good
14 organization?

15 A. I certainly wouldn't want to
16 represent that -- this is a huge, huge, huge --
17 this is, in essence, the chairman who I'm
18 interacting with. I would not want to
19 represent that I would agree with or -- you
20 know, saw or would agree with any -- their kind
21 of promotional stuff.

22 Q. Your interactions with them, you
23 were -- you found your interactions with them
24 good ones?

1 A. With Paul, I never found Paul --
2 Paul never raised anything -- any red flag in
3 my --

4 Q. Okay.

5 A. -- mind.

6 Q. Okay. Now, you also have several
7 corporate boards and compliance committees:
8 Immunocorp, 2011 to the present; TPG, as a
9 senior advisor, 2008 to the present; Aptalis,
10 2011 to 2014; Tokai, 2009 to 2017 as a board
11 member; Google Health Advisory Council;
12 Revolution Health Group, as a medical advisory
13 board; and Perseus, on the advisory board; and
14 then --

15 A. Perseus.

16 Q. Perseus. Sorry.

17 -- and then 2000 to 2003,
18 Perseus-Soros, which I assume is related here.

19 So sir, first of all, in your
20 capacity as the chair of compliance committees,
21 have you ever -- have you ever had any
22 responsibility for a CIA?

23 A. I -- there was one issue at one
24 point in time with Aptalis.

1 I don't think -- I'd have to go
2 back and check with -- with counsel. I don't
3 recall being involved in any CIA activity.

4 But there was one legal issue I
5 remember coming up, but it was years ago. And
6 I just apologize. I don't have a recollection.
7 I'd have to check with counsel.

8 Q. Do you --

9 A. Let me say, I don't believe I was
10 ever involved. Whether the company was ever in
11 any discussions, I don't know that.

12 Q. Okay.

13 A. I just can't recall.

14 Q. Do you know if --

15 MR. LAVELLE: Excuse me. I'm sorry
16 to interrupt, but I just got a note from
17 one of the attorneys participating by
18 phone. They can't hear anything.

19 (A discussion was held off the
20 record.)

21 BY MS. FREIWALD:

22 Q. Do you know, sitting here today, if
23 Aptalis had a CIA?

24 A. I can't recall.

1 Q. Okay. Have you been responsible
2 for any kind of a leadership role in any
3 CAI-like [sic] agreement, where you -- where
4 you had to shepherd an organization through a
5 change in compliance culture?

6 A. I'd want to refresh my memory --
7 I'd want to refresh my memory of those facts.
8 Sitting here today, I wouldn't phrase it like
9 that. It just -- off the top of my mind, I'm
10 just -- the facts are just not clear to me.
11 I'd have to do a little homework.

12 Q. So I really don't want to nitpick
13 at words with you, so I'm trying to ask the
14 question broadly.

15 Have you played a role, not -- in
16 any way with regard to any kind of compliance
17 revamping in any for-profit company?

18 A. Sure. I mean, "revamping" I think
19 is probably a good word. There are -- you
20 know, in any global company, there are always
21 issues that come up and that had to be handled,
22 and I've been part of that handling, whether
23 they are --

24 I don't think they rose to CIA.

1 I'd have to go back and review it. But there
2 were certainly compliance issues that I was
3 involved in and responsible for helping lead
4 the organization at a board level.

5 Q. Okay. And can you tell me, without
6 getting into details or even what the company
7 is, what type of revamping you're talking
8 about?

9 A. I mean, you find that, you know,
10 in -- for example, in certain countries -- I
11 mean, I want to be careful, without talking to
12 counsel. I don't know what's -- I probably
13 should talk to counsel before -- of those
14 companies to know what -- what specific --

15 I mean, you find that there are
16 things that may be out of regulatory compliance
17 that you -- I mean, you know, it's not just a
18 one-off and that you have to bring back into
19 compliance.

20 And I have been involved in --
21 actually, I can think of two episodes. I
22 wouldn't want to get into details, because I
23 think those are corporate confidential.

24 But I've been involved in at least

1 two times where there are things that -- where
2 compliance would be questioned, and you have to
3 work through those compliance issues.

4 Q. And have you been involved with
5 regard to any marketed pharmaceutical products
6 where there were issues around the marketing?

7 A. Marketed pharmaceuticals? Well,
8 the products are marketed.

9 Q. On the -- yeah, on the market.

10 A. They were marketed -- so the
11 products were marketed, and there were
12 compliance issues, yes.

13 Q. Okay. And do you know if they were
14 compliance issues that were identified entirely
15 internally or whether they were the subject of
16 discussion with some kind of external
17 regulatory or enforcement body?

18 A. I recall one of both.

19 Q. And was there some period of time
20 of oversight that you were involved in?

21 A. Yes.

22 Q. And was there some resolution on
23 that?

24 A. Yes.

1 Q. And did you feel after that period
2 of resolution that the company was able to go
3 forward in a positive way?

4 A. That's a little bit of a broad
5 overstatement, right. Again, you're asking
6 about feelings.

7 Q. Did you believe, based upon what
8 you had observed and the changes that you had
9 seen put into place, that the company could
10 make changes and could implement them in a good
11 way going forward?

12 A. I think that would probably be
13 fair.

14 Q. Okay. And --

15 A. I mean, not without some -- you're
16 never completely -- I mean, whenever you're on
17 a board, you never breathe a complete sigh of
18 relief. Is that fair?

19 Q. And that's appropriate, correct,
20 because you always have to be vigilant,
21 correct?

22 A. Right. And you also -- right. I
23 think that's fair.

24 Q. And all companies do, correct? All

1 companies have to --

2 A. I don't want to speculate for all
3 companies, but --

4 Q. You wouldn't want to speculate that
5 all companies should be -- should be vigilant
6 with regard to compliance?

7 A. Should be?

8 Q. Yeah.

9 A. Absolutely.

10 Q. Okay.

11 A. I'd be happy to agree with that.

12 Q. Okay. And -- and I gather that the
13 fact that these companies had -- whatever the
14 companies are. I'm not pointing to any
15 particular company, because I don't -- I'm not
16 asking you to disclose.

17 The companies that you were
18 involved in that had compliance issues, you
19 were comfortable continuing your association
20 with them?

21 A. That would be fair.

22 Q. Okay. And you were comfortable
23 believing that there was a course of conduct
24 going forward where they could kind of right

1 the -- right the ship?

2 A. Correct the action.

3 Q. And did any part of that involve
4 you interfacing with the FDA to ensure that the
5 FDA was satisfied?

6 A. On those two instances, no.

7 Q. Did any part of it involve them
8 providing information either to FDA or to some
9 other governmental body with regard to specific
10 changes that were being made?

11 A. Yes.

12 Q. And did it involve even changes in
13 documents? SOPs, for example.

14 A. One instance, sort of. The other,
15 I don't think it would be characterized that
16 way.

17 Q. Did it involve changes in training
18 employees?

19 A. One -- one likely did.

20 Q. Did it involve changes in the
21 processes and procedures for the compliance
22 department?

23 A. One likely did.

24 Q. Did the organizations have

1 compliance departments prior to them getting
2 into an issue?

3 A. They had quality departments.

4 Q. Okay. And did they --

5 A. Well, one had a quality department.
6 The other, I'd have to refresh my memory.

7 Q. Did either/or both of them move to
8 having a compliance department after they had
9 an issue?

10 A. No. It remained as a -- it remains
11 as a quality department.

12 Q. Okay. And did they go through a
13 period where they were being monitored?

14 A. By whom? When you say
15 "monitored" --

16 Q. By either -- I was thinking at the
17 time by some external body.

18 A. No. That was not -- these did not
19 rise to that level.

20 Q. Okay. Did they go through some
21 period of internal monitoring?

22 A. Sure. I mean, I'd have to review
23 exactly how formal, but certainly nothing -- I
24 mean, there's -- there would be continued

1 oversight, would be the proper answer.

2 Q. Okay. And was there any time where
3 they -- where your role as -- in a compliance
4 function was specifically tied to your FDA
5 experience?

6 MR. RAFFERTY: Object to the form.

7 A. Certainly I -- certainly I, you
8 know, draw upon my FDA experience. I'm not
9 sure exactly what you mean.

10 Q. I think I asked the question badly.
11 Did what you needed to do from a
12 compliance standpoint implicate your FDA
13 experience?

14 A. Sure. I think that would be fair.

15 Q. Okay.

16 A. I mean, I think I relied on my
17 FDA -- my knowledge of FDA regulations. I
18 think that would be fair.

19 Q. Okay. And at the time that you
20 were involved in this, were there any
21 terminations of any personnel who were involved
22 in the issue that led to the compliance --

23 A. I'd have to go --

24 Q. -- revamping?

1 A. Sorry.

2 I'd have to go back and look at the
3 record.

4 Q. Did you feel that you could
5 continue to engage with employees who had been
6 there at the time of the problem and still move
7 forward in an appropriate way afterwards?

8 A. Yeah. So let me -- let me clarify.
9 In one instance, this had to do with -- I think
10 actually in probably both instances, this had
11 to do with prior leadership and prior ownership
12 of the company that you end up inheriting.

13 So it was basically a different
14 ownership and different -- is my recollection,
15 that these problems existed prior to the
16 existing management or the ownership.

17 Q. And what about the other one?

18 A. Well, both problems, I believe --
19 I'd have to check dates -- I think they -- I'm
20 actually sure. Both pre- -- started -- they
21 were historical problems that basically we
22 uncovered.

23 Q. Okay. But did employees stay on --
24 employees who were part of those historical

1 problems stay on and move forward after the fix
2 or the revamping?

3 A. Well, so I don't think that the --
4 the people that I was dealing with sort of
5 inherited the problem of a prior ownership, I
6 think would be the way to say it.

7 Q. Okay. Would you agree with me that
8 the FDA at all times relevant to this case knew
9 that prescription opioids had a potential for
10 abuse and misuse?

11 MR. RAFFERTY: Object to the form.

12 A. I think that's probably -- well,
13 whenever you say "the FDA," it's -- you know, I
14 assume you're talking about somebody at FDA.
15 And I think that -- I think the answer would be
16 yes, but maybe not fully to the extent that
17 there was.

18 Q. Would you agree with me that at all
19 relevant times, FDA understood the Class II
20 opioids had an abuse potential similar to
21 morphine?

22 A. Yes, I would again agree with you
23 on that, but again, I just -- with the same
24 caveat.

1 Q. Would you agree that Schedule II
2 controlled substances are defined as substances
3 that have a high potential for abuse which may
4 lead to severe psychological or physical
5 dependence?

6 A. I think you're reading the schedule
7 correctly, so I would agree.

8 Q. Would you agree that only -- that
9 the only level higher than Schedule II would be
10 Schedule I, and Schedule I products have no
11 currently accepted medical use in the United
12 States, a lack of accepted safety for use under
13 medical supervision, and a high potential for
14 abuse?

15 A. Correct.

16 Q. Would you agree that at all
17 relevant times, FDA knew that extended-release
18 opioids, if crushed or chewed, would not
19 function as extended-release products but would
20 release their drug immediately?

21 MR. RAFFERTY: Object to the form.

22 A. I think the people who were focused
23 on opioids would know that. I'm not sure if,
24 quote, FDA knew that, but I think some people

1 at FDA.

2 Q. FDA reviewers of opioid products
3 would know that?

4 A. Yeah, I think that -- I think
5 Curtis articulated that early on. I'm not sure
6 how many others at the time focused on that.

7 Q. Okay. Would you agree that FDA
8 knew that extended-release opioids might be
9 crushed or chewed by people accidentally,
10 including elderly people or people with
11 swallowing problems, and that that was
12 something they were concerned about?

13 MR. RAFFERTY: Object to the form.

14 A. Yeah, I don't -- I don't remember
15 that. I don't have -- I couldn't tell you
16 firsthand what the extent of concern was. I
17 didn't see that, I mean, phrased that way, but
18 I'm not saying that somebody did not.

19 Q. Okay. Does it ring any bells to
20 you that the FDA was focused on the potential
21 that people would crush or chew
22 extended-release products in order to
23 facilitate their appropriate use, not to
24 deliberately abuse them, and that they could

1 get into a problem doing that?

2 A. I didn't have any conversation, and
3 I am -- I'm just blocking on the record talking
4 about that. I may just -- I just don't have a
5 recollection --

6 Q. Okay.

7 A. -- of the record talking about
8 that. You'd have to go back -- I mean,
9 obviously, there was an early -- FDA --

10 Q. If you don't remember, that's fine.

11 A. Well, I do remember certain pieces
12 of this.

13 Q. Okay.

14 A. I just want to let you know about
15 what FDA knew about crushing and -- but I'm not
16 sure I fully tie -- have a recollection of
17 tying the crushing to elderly and that
18 discussion. I'd just have to review the record
19 to double-check that.

20 Q. Are you aware of FDA understanding
21 that extended-release opioids might be crushed
22 or chewed by abusers?

23 MR. RAFFERTY: Object to the form.

24 A. Sort of yes and no. Mostly yes.

1 Q. Right.

2 A. Mostly yes. There was some early
3 crushing studies that they -- they were aware
4 of that, and they didn't -- they didn't flag
5 this part of it. So that's why I'm just -- but
6 Curtis certainly did flag this.

7 Q. Certainly for most of the timeline
8 that we're talking about, that was something
9 they were aware of?

10 A. Yeah. Early on, there wasn't the
11 same focus, because there was the solution
12 pretty easily of some of these products,
13 that -- if I remember the studies by the
14 reviewers -- and they didn't note this. So
15 that was why I point this out.

16 Q. Would you agree with me that they
17 understood the potential to crush these
18 products?

19 MR. RAFFERTY: Object.

20 Q. They did crush studies, right?

21 A. There was -- FDA did do a study
22 early on, or there was -- I'm sorry. I
23 misspoke. You'd have to pull the study -- the
24 FDA comments. I don't know if -- FDA may

1 have -- I believe FDA reviewed the study
2 results early on. I don't believe FDA did the
3 study. But I could be wrong.

4 Q. Would you agree with me that FDA at
5 all relevant times knew that opioids carry a
6 risk of respiratory depression?

7 MR. RAFFERTY: Object to the form.

8 A. Sure. I think that would be a fair
9 statement, with all the caveats that I just
10 gave.

11 Q. And would you agree that FDA at all
12 relevant times knew that patients on opioids
13 may develop tolerance?

14 MR. RAFFERTY: Object to the form.

15 A. You know, the easy answer is, sure.
16 I'm just trying to think --

17 I mean, I led the addiction team
18 back in 1990s on certain products, as you know,
19 that were sort of unrelated to what's at issue
20 today.

21 And FDA wasn't -- didn't have a lot
22 of expertise on tolerance. We looked at NIDA
23 and others. That's the only reason I'm
24 hesitating.

1 Q. Okay. But the general concept of
2 opioid tolerance was certainly known at all
3 times?

4 MR. RAFFERTY: Object to the form.

5 A. The word was known, okay? I mean,
6 I don't think there was the kind of expertise
7 to really understand the full implications of
8 tolerance at the agency.

9 Q. And was there an understanding that
10 opioids were not the only class of drugs to
11 which people could become tolerant?

12 MR. RAFFERTY: Object to the form.

13 A. Again, at a very simple level,
14 there's some truth to your statement.

15 But again, you're dealing with very
16 different -- it would be misleading to say that
17 the tolerance of those other compounds is the
18 tolerance of opioids, because the neural
19 adaptations that would lead to tolerance are
20 very different and the neural pathways are very
21 different.

22 So when you're talking about, did
23 FDA understand this, I don't think so.

24 Q. Different -- different types of

1 drugs, but there are -- opioids are not the
2 only class of drug to which patients can become
3 tolerant?

4 A. No. But understand, tolerance is a
5 word -- the need for higher --

6 Q. Doses.

7 A. -- doses because of a failed -- but
8 the -- but the mechanism and the neural
9 mechanism by which that occurs can be very
10 different.

11 Q. Yeah, I'm not --

12 A. So using the word "tolerance" is
13 sort of an easy word to use in a complex
14 understanding of the biochemistry and the
15 neural adaptations.

16 Q. Blood pressure medicine, steroids,
17 people can become tolerant to them and over
18 time require higher doses to achieve the same
19 effect?

20 A. Yes and no. The neural adaptations
21 are very different.

22 Q. Okay. But within those drugs,
23 you -- patients may need higher doses over time
24 to achieve the same effect?

1 A. No. Patients -- well, I mean,
2 it's -- the answer is, it's complicated.

3 Q. So -- and there were data -- strike
4 that.

5 Would you agree that FDA at all
6 relevant times knew that patients on opioids
7 may develop physical dependence?

8 MR. RAFFERTY: Object to the form.

9 A. Again, a term that is easily
10 bandied about, but I don't think -- I think
11 very few people at the agency really understood
12 physical dependence and addiction and how they
13 overlap.

14 So I think they would -- they could
15 use the term. They could repeat the mantras.
16 But I don't think there was a great depth of
17 understanding.

18 Q. Well, I'm not asking you, sir,
19 whether people had every piece of understanding
20 20-plus years ago, almost a quarter century
21 ago, that they have today.

22 But I am asking you whether the
23 concept of physical dependence to opioids was
24 understood. Would you agree with me --

1 A. I don't think --

2 Q. -- that was known?

3 MR. RAFFERTY: Object to the form.

4 A. I mean, not to be argumentative,
5 but I don't think the concept of physical
6 dependence is understood by anybody, even
7 today, fully. I think there's still scientific
8 questions about that.

9 Q. And I just said, not fully. We're
10 talking about almost a quarter century ago,
11 right?

12 A. Sure.

13 Q. I mean, just to -- just to be
14 clear. You know, I would hope we've all
15 learned things over the last quarter century in
16 all kinds of aspects.

17 But dependence was a concept that
18 was known with regard to opioids at all times
19 that are relevant to the approval of the
20 products that you have opinions about?

21 MR. RAFFERTY: Object to form.

22 A. "Dependence" was a term that was
23 used. What was clearly understood were, these
24 were addictive products and powerfully

1 addictive products, and there were terms like
2 "dependence" that was used.

3 Q. I'm not asking about addiction
4 right now. I'm asking about dependence,
5 physical dependence.

6 A. I can't -- I mean, these are
7 complicated terms that we could spend hours on.
8 And if you're asking me, then, for people to
9 understand -- if you want to ask me whether FDA
10 understood physical dependence, you have to
11 understand how physical dependence and
12 addiction were related.

13 Q. Do you agree that there was
14 language with regard to dependence in the
15 labels for these products from the beginning?

16 A. Correct. The manufacturers put
17 them in, and FDA allowed them to be in.

18 Q. Is that your testimony as to how it
19 happened? Are you -- are you testifying that
20 the manufacturers asked for language about
21 dependence, and FDA said, Okay?

22 A. No. What I'm saying is that the
23 label is the manufacturer's and the label is
24 owned by the manufacturer, and I'm saying that

1 I don't see FDA striking that language.

2 Q. Okay.

3 A. But --

4 Q. You don't know if the FDA required
5 that language?

6 A. So I do know that the -- the label
7 was submitted by the company, and I believe
8 that language was in going back to '92 about
9 it, but I think it was the company and
10 Retter's [ph] documents in '92, when he sends
11 them over to the agency, that had that.

12 Q. Well, I mean, look. Come on.
13 Let's just -- I will grant you that the first
14 draft of the label will come from companies,
15 but I also don't think that we have to dance
16 around this.

17 The FDA would have expected
18 language about tolerance and dependence in the
19 label, and it was in the label, correct?

20 MR. RAFFERTY: Object to the form.
21 Move to strike the preamble, the
22 commentary.

23 A. I don't think -- I don't see any
24 guidance or instructions or class-wide labeling

1 instructions that say that that had to be in.
2 I mean, I don't want to -- let me just finish
3 if I may.

4 I don't know -- we could have a
5 discussion and try to figure out if one just
6 said these were addictive products, right, and
7 the risk of addiction -- I don't know whether
8 FDA -- I'd have to go back and think about it,
9 whether that would be sufficient.

10 Q. Do you remember what the product
11 said about addiction at the time of initial
12 approval?

13 A. Which product are you talking
14 about?

15 Q. Well, any -- any product. Let's
16 start with OxyContin.

17 A. Well, it certainly had a -- the
18 Schedule II statement. This was similar to
19 morphine, right?

20 Q. Do you remember what else it said
21 about addiction?

22 A. There were statements on iatrogenic
23 addiction, I believe, in the label, and there
24 was a statement that was a "reason to believe"

1 statement in the label.

2 Q. Just so I'm clear, are you
3 testifying that having language about tolerance
4 and dependence in the label was somehow a bad
5 or misleading thing?

6 MR. RAFFERTY: Object to the form.

7 A. I'm not -- I'm saying that to the
8 extent that one can talk about -- to the -- to
9 the extent that one talks and trumpets
10 dependence and tolerance as distinct from
11 addiction and don't -- you can go to higher
12 doses because this is just tolerance or
13 dependence and this is not addiction, I think
14 was very dangerous.

15 Q. Do you know of any scientific
16 textbook that refuses to draw any distinctions
17 between tolerance, dependence, and addiction?

18 A. Complete distinctions? Yes. I
19 think there's significant writing that talks
20 about -- there may be definitions over time
21 that tries to make distinctions, but there's
22 also considerable literature about overlap
23 between those and how dependence --

24 I mean, in the end of the day,

1 certainly when you're dealing with opioids,
2 that dependence, I mean, is likely to be all
3 addiction.

4 Q. Well, are you saying that you
5 have -- there's no space in which you
6 distinguish between dependence, which can be --
7 which can include a patient who's properly
8 managed and functioning in every way in their
9 life, and addiction and addictive behaviors,
10 dysfunctional addictive behaviors?

11 MR. RAFFERTY: Object to the form.

12 A. No, I'm not saying there's no
13 space.

14 I think if you take a hundred -- I
15 mean, my clinical judgment would be, if you
16 take a hundred people and you expose them to
17 your client's product at high doses for a year,
18 you'd probably find some 30, 40 percent likely
19 to be able to stop.

20 You'd probably find another 30-plus
21 percent that are able, after either tapering
22 or -- to have symptoms and have difficulty, and
23 I think you'd probably have 20-plus percent
24 having compulsive behavior. And so I think

1 there's a continuum between that.

2 Now, whether that is -- you want to
3 call that middle category dependence or you
4 want to call that a continuum on addiction and
5 whether those neural networks are different, we
6 could spend hours.

7 Q. Is that 20 percent number from a
8 particular source or sources you can cite me
9 to?

10 A. Those are in discussions I've had
11 with experts over the years. That's my, you
12 know -- that's my judgment. That's --

13 Q. So you're not relying on any
14 particular authority for that?

15 A. No -- well, I can. I mean, if you
16 look at -- I'm happy to go through -- there are
17 significant studies on the effect of high
18 doses, and we can go through all of them and --

19 Q. I'm looking for the 20 percent
20 number.

21 A. Yeah.

22 Q. That's a clinical impression or --

23 A. No --

24 Q. -- conversation --

1 A. -- but I -- so that came -- I mean,
2 certainly, I mean, from the clinical --
3 clinical experience and from discussions.

4 But if you look at, I think, the
5 literature as a whole, I think -- I'm sure
6 other addiction experts will testify on this --
7 I think that's certainly within the range that
8 you see in a number of studies for people who
9 have been on high dose.

10 Q. How many patients have you managed
11 on opioids?

12 A. I've managed a number, but I've --
13 I certainly have --

14 Q. What's -- what the number?

15 A. Handfuls, probably, over the years.

16 Q. Did you ever have a pain practice?

17 A. No, I -- no, but I've been a
18 hospitalist. I've been on the wards.

19 But as I said to you, that that
20 number -- I'm sorry.

21 Q. I mean, you've never had a patient
22 population where you're treating them for pain
23 and you're managing their therapy on a regular
24 basis?

1 A. I certainly have had -- I've had
2 some of the sickest patients, I mean, who have
3 had -- that I've been responsible for who have
4 been in excruciating pain and that I was
5 responsible for their cancers.

6 Q. Since being at FDA?

7 MR. RAFFERTY: Object to the form.

8 A. Certainly after I was on -- after
9 FDA, when I was on the wards. I mean, not
10 recently. I've stepped back. But certainly
11 when I've been on the wards. I did a lot of
12 adolescent medicine, and I could assure you I
13 did a lot --

14 Q. When you were on the wards. When
15 were you on the wards?

16 MR. RAFFERTY: Please let him
17 finish. He's being very responsive to
18 your question, and you have interrupted
19 him three or four times in a row.

20 Q. I certainly don't mean to, but I'm
21 just trying to get the orientation of a date.
22 Because I asked for a date, and I'm very
23 unclear what you're talking about.

24 A. Right. So both before and after

1 FDA, I was attending hospitalist. We didn't
2 call it hospitalist back -- but I did a lot of
3 adolescent medicine, and adolescent medicine is
4 a lot of oncology. So -- and that involved
5 sometimes significant pain patients.

6 Q. So let's put aside the before FDA,
7 since that was before 1990, and focus just on
8 the after, after '97. How much of your time
9 have you spent as a hospitalist since 1997?

10 A. So I stopped probably -- oh, I
11 don't know. Certainly did it at Yale pretty
12 extensively, maybe did it a month, a year. I
13 was the attending on the floor. Did it a
14 little less at UCSF. But I was pretty actively
15 involved.

16 Q. Did you ever have a private
17 practice after -- of medicine after getting out
18 of FDA?

19 A. I never had a private practice
20 before or after.

21 Q. Okay. And you never were the
22 primary doctor prescribing prescription opioids
23 for patients on an -- on an outpatient basis?

24 A. As I said, I was a hospitalist, and

1 any use of opioids, you know, would have been
2 probably morphine at the time, and it was in
3 the sickest of patients.

4 Q. Okay. So you were seeing morphine
5 use in the sickest of patients. And they were
6 all pediatric patients?

7 A. That would be what I would be
8 taking care of.

9 Q. Okay. So --

10 A. I mean, occasionally you get a --
11 occasionally you get an adult who you followed
12 as a child. So I just wanted -- so I've taken
13 care of some of those.

14 Q. Did you look at -- in preparing
15 your report, did you look at NSDA data on rates
16 of misuse of prescription opioids over time or
17 for any period of time?

18 A. I've looked at some general abuse
19 data, but I have not studied specifically -- I
20 can give you certain abuse trends over time and
21 am happy to discuss that.

22 Q. Could you -- do you know what the
23 prevalence of non-medical use of prescription
24 opioids is per NSDA data over time?

1 A. I have -- I think I have that.
2 You'd have to give me a minute, if you want me
3 to find it. I'm happy to do that.

4 Q. Are you aware that looking over
5 time, from, like, 2002 to 2017, something like
6 that, it's somewhere around 1 percent?

7 MR. RAFFERTY: Object to the form.

8 A. The 1 percent misuse? I'm sorry.
9 I don't understand the 1 percent.

10 Q. Yeah, non-medical use/misuse
11 prevalence.

12 A. That only 1 percent of opioids are
13 misused? Is that what you're saying?

14 Q. New non-medical use, I think. Have
15 you seen those numbers?

16 A. I'm a little confused. Let me go
17 check. I mean, I think that I'm -- I'm
18 certainly familiar with the numbers of
19 conversion from prescription drugs by doctors
20 to non-medical use and those, but those are a
21 different set of numbers.

22 And I'm also aware of the surveys
23 of people admitted to residential facilities or
24 for treatment, and the percentage that

1 started --

2 But I certainly am not aware that
3 only 1 percent of opioids in this country are
4 misused, by that data. I'd have to go back and
5 look. I find that --

6 Q. You've got to give me one second,
7 because I just lost my microphone.

8 MS. FREIWALD: Can we go off the
9 record for a second.

10 VIDEO OPERATOR: 3:02, we are off
11 the video record.

12 (A discussion was held off the
13 record.)

14 VIDEO OPERATOR: 3:04, we're on the
15 video record.

16 BY MS. FREIWALD:

17 Q. Sir, would you agree with me that
18 FDA at all relevant times knew that some
19 patients wanting to stop opioid therapy would
20 have to be tapered to avoid symptoms of
21 withdrawal?

22 MR. RAFFERTY: Object to the form.

23 A. Again, I don't think it's a
24 complete sentence -- complete thought.

1 I mean -- but I think there
2 would -- probably correct to say that FDA
3 recognized that some patients would -- should
4 be tapered. I think that would be correct.
5 Some patients, you know, I mean, could not be
6 tapered and would be addicted, I think would
7 also be part of that sentence.

8 Q. Okay. And from your review of the
9 record, would you agree that FDA knew that
10 pseudoaddiction, whether it was called
11 pseudoaddiction or not called that, that -- it
12 was a concept that was described in the
13 literature going back to the '80s, if not
14 before?

15 A. I think that's the way it was
16 represented to the agency, if I'm correct. I
17 think it was represented that way, that it was
18 in the literature.

19 Q. Have you, as part of your report in
20 this case, gone to the literature to see --

21 (Interruption.)

22 Q. Have you, as part of your report in
23 this case, gone to the literature to see how
24 far back the concept that is now referred to as

1 pseudoaddiction was described, whether by the
2 name pseudoaddiction or some other name?

3 A. The Haddox and Weisman --

4 Q. Yeah.

5 A. -- article? What? '80-something.

6 Q. I'm asking a slightly different
7 question --

8 A. Sure.

9 Q. -- because I think we can agree
10 what -- the date of the Haddox and Weisman
11 article. Yeah. I mean, that's --

12 A. Sure.

13 Q. What I'm asking is if you looked to
14 see if prior to that article there were
15 discussions of the concept without using that
16 name.

17 A. I've tried to look historically to
18 understand that theory. I've tried to look at
19 that.

20 Q. Do you have any kind of a
21 bibliography as part of your report that
22 includes the pre-1988 or '89 literature
23 describing the concept?

24 A. I think you would have to go back

1 and look at the scientific articles. I believe
2 there were -- there was a -- I did include very
3 significant number of literature of what was
4 known prior to, certainly, '95 that goes back
5 several decades.

6 So if you look at that bibliography
7 on scientific articles, I think there are --
8 there are a significant number of historical
9 articles.

10 Q. I'm asking a specific question. If
11 I look at your bibliography, will I find that
12 you pulled articles pre-1989 that discuss what
13 came to be talked about as pseudoaddiction?

14 A. I think that -- we'd have to go
15 back and double-check, but I would -- I think
16 that's correct, because I think I -- I searched
17 very -- very -- tried to search very carefully
18 the production as on -- and the historical
19 documents, because there are some compilations
20 of that science by your client in certain
21 documents.

22 And I have gone through some
23 400-page compilations of all the -- of all
24 the --

1 Q. Okay.

2 A. -- science that they had access to
3 in the '90s. So I went through those -- those
4 studies.

5 Q. So based upon your review, would
6 you agree with me that while the term
7 "pseudoaddiction" may not have been used, the
8 concept was used in the literature prior to
9 1989?

10 A. I'd have to review that literature
11 before I can answer that question accurately.

12 Q. Would you agree that for almost the
13 last quarter century, which is what we're
14 talking about in this case, FDA has not been
15 willing to restrict the use of prescription
16 opioids as a class -- there have been some
17 limited exceptions -- to any underlying
18 specific disease state?

19 MR. RAFFERTY: Object to the form.

20 A. As a class? No, I think -- I think
21 you're correct. I think that if you look,
22 you'll see -- I don't want to say a
23 patchwork -- I think that would be -- but a
24 patchwork of indications and sometimes maybe

1 even inconsistencies. So I don't think there
2 is a class-wide label recommendation.

3 Q. What I'm asking you is, generally
4 speaking, for the class, they have not been
5 willing to limit the indication to any specific
6 underlying disease --

7 MR. RAFFERTY: Object to the form.

8 A. That's --

9 Q. -- that is the cause of pain?

10 A. That's -- well, we know that's --
11 we've talked about cancer. We've talked about
12 Actiq. We've talked about Oralet. And those
13 are disease-specific.

14 The agency did not believe that the
15 studies on those -- on the other underlying
16 diseases, such as -- the agency didn't -- I
17 mean, concluded --

18 Q. Sir --

19 A. Let me just finish.

20 The agency concluded that there was
21 not substantial evidence to use opioids in
22 those conditions other than cancer. So there
23 was not substantial evidence to use it in hip
24 or in OA. I think the record reflects that.

1 Q. Sir, that's not my question. I'm
2 just going to ask you to listen to my question.
3 We have limited time here.

4 So I understand there are a couple
5 exceptions that we've talked about. But as a
6 general matter, the FDA has not been willing to
7 limit prescription opioids, including
8 extended-release prescription opioids, to
9 treatment for any specific underlying disease
10 state?

11 MR. RAFFERTY: Object to the form.

12 A. The question to me is confusing,
13 because in order to do that, you need
14 substantial evidence, and substantial evidence
15 doesn't exist with regard to those underlying
16 disease states, according to the agency.

17 Q. Has the FDA been asked to limit
18 opioid use to certain specific diseases and
19 said no?

20 A. We can pull up the proposition to
21 see exactly what the request was. I don't
22 think that was in the proposition. I think it
23 was dose. But I'd have to refresh my memory on
24 that. I don't think that was part of PROP.

1 Q. Has FDA ever been willing to limit
2 extended-release opioids to cancer pain?

3 A. I think I testified --

4 Q. With the exception of the couple --
5 the couple of things you've talked about.

6 MR. RAFFERTY: Object to the form.

7 Q. And I'm focusing on the
8 extended-release.

9 A. So Duragesic was extended-release,
10 and I -- and I read you the statement this
11 morning that I was not willing to limit it just
12 to cancer. I thought there would be some few
13 patients beyond cancer.

14 But again, your question is
15 somewhat confounding, because it's backwards.

16 Q. It's actually very -- very simple.
17 There have been requests since 1996 --

18 I'm in the post-you-as-Commissioner
19 time period.

20 A. Right.

21 Q. There have been requests, I think
22 we should be able to agree, to limit
23 extended-release opioids to cancer pain, and
24 the FDA has declined, correct?

1 A. You'd have to show me
2 specifically --

3 MR. RAFFERTY: Object to form.

4 A. -- what you're referencing to
5 refresh my memory.

6 Q. The FDA has not been willing to
7 limit the indication for extended-release
8 opioids to any specific number of days, have
9 they?

10 MR. RAFFERTY: Object to the form.

11 A. The FDA has stated -- well, with
12 regard --

13 Q. It's really a yes-or-no thing.
14 They've not been willing to --

15 MR. RAFFERTY: He's allowed to
16 answer your question. Asking whether
17 the FDA has been willing to is vague,
18 and it's ambiguous, and he's been
19 answering the question.

20 Q. They've -- have they -- I asked
21 you, they've done it? Have they -- have they
22 ever taken the view that that is the correct
23 thing to do?

24 A. I think the agency in the -- in the

1 current label says -- we could get the actual
2 language -- is fewest doses, lowest dose. I
3 believe that's in the current label. I may not
4 have the exact words correct.

5 But I don't think FDA, again, in
6 trying to walk this balance, set a threshold.
7 But I think it was -- it's clear that the FDA
8 did adopt the CDC view of, fewest days would be
9 appropriate.

10 Q. Okay. So we'll look at that
11 language later.

12 Putting aside the 2017 change,
13 prior to 2017, has the FDA imposed any number
14 of day limits on the use of extended-release
15 opioids?

16 A. I don't believe the agency has that
17 to -- to impose -- quote, impose that.

18 Q. My question is, have they at any
19 point come to a conclusion -- through any
20 advisory committee or in response to any
21 citizens' petition or review of any company
22 product, have they come to the decision that
23 the label should be changed in that way?

24 A. I don't -- I'm not privy. I

1 understand that there are label changes that
2 are under discussion, and I'm not privy right
3 now.

4 I've spoken to the prior -- the
5 now -- Dr. Gottlieb. I understand there's
6 label changes that are under -- that are being
7 thought about, but I'm not -- I didn't push him
8 on exactly what those were that are being
9 thought about. So I can't comment.

10 Q. As far as you know, there's never
11 been a recommendation from any FDA advisory
12 committee that extended-release opioids should
13 be limited in use to a specific number of days?

14 A. Before -- I can't answer that. I'd
15 have to go back. I have the transcripts. We'd
16 want to search. I can't tell you there wasn't
17 a recommendation by members of the advisory
18 committee to limit that. There were a number.
19 I'd have to go back.

20 That question I don't believe was
21 posed to the advisory committee as such, for
22 which there was a vote, but I'd have to go back
23 and check the record.

24 Q. Sitting here today, as part of your

1 opinion, that's not something you know the
2 answer to?

3 A. Whether the FDA -- whether an
4 advisory committee member recommended that?
5 I'd have to go back and check.

6 Q. I didn't say -- I didn't say
7 advisory committee member.

8 Whether an advisory committee ever
9 reached a vote or -- whether in response to a
10 citizens' petition or in any other way, did the
11 FDA ever come forward and come to the
12 conclusion that that was -- that it was
13 appropriate to change the labels for
14 extended-release opioids to limit their use to
15 a certain number of days?

16 A. My discussions with Dr. Woodcock is
17 that she was not ready to do that over the
18 years because she wanted -- she didn't think
19 there was the science to do that that would
20 create a precise number, that the science was
21 still out.

22 So I -- so I hope that answers your
23 question.

24 Q. And has the FDA, as the result of

1 any advisory committee --

2 A. I think -- she been opposed to a
3 hard-and-fast rule, I think would be the better
4 way to say it.

5 I think the agency did agree --
6 there's a strong view that it should be -- you
7 know, we're really talking about least number
8 of days, lowest doses, and get off these drugs
9 as soon as possible. I think that's the
10 general view.

11 Q. And I promise, we will look at
12 specific labels when we -- when we are a little
13 later in the deposition.

14 But for now, I'm trying to talk
15 across products. So trying to not limit myself
16 to one company's label.

17 And you may know things I don't
18 know. So if I ask the question broadly, I'll
19 hear what your answer is.

20 I want to ask you essentially the
21 same question with regard to maximum MMEs. Has
22 the FDA, through any advisory committee process
23 or any other internal review process,
24 including, say, review of a citizens petition,

1 to your knowledge, ever come to the conclusion
2 that MMEs should be maxed at a certain daily
3 level?

4 A. So I don't think -- from a
5 regulatory perspective, we certainly have the
6 agency on record saying that they believe there
7 is an association between higher doses and
8 addiction and risks and overdose.

9 We -- but we -- but they refused
10 that -- they didn't know a precise threshold,
11 so they backed away, but they recognized there
12 was an association. But again, I think they do
13 support the concept of lowest effective dose.

14 Q. But they've been reluctant to
15 create any hard-and-fast rules?

16 A. I think that's -- they've been -- I
17 think that -- and I think that's possibly one
18 of the criticisms, is that -- or one of the
19 pluses, depending on your perspective, is
20 Dr. Woodcock has been trying hard to walk this
21 balance.

22 And I think -- I think when the
23 agency looks back and says, yeah, maybe we
24 didn't do things fast enough, these are the

1 kinds of questions that it's -- that it's
2 troubled by that it has not acted.

3 Q. And would it also be true that they
4 have not been willing to write into the label
5 any language about evidence of improved
6 function --

7 MR. RAFFERTY: Objection.

8 Q. -- with opioid therapy?

9 MR. RAFFERTY: Object to the form.

10 A. They're certainly in many -- again,
11 I know you're prefacing your question broadly,
12 but they certainly have been very clear in the
13 DDMAC letters of a number of your colleagues
14 around the table that there is not substantial
15 evidence on function.

16 Q. I'm asking a different question.
17 We'll talk about function claims later.

18 I'm asking whether --

19 A. How many days is this deposition
20 going?

21 Q. I'm -- I'm asking --

22 MS. LEVY: Objection.

23 Q. I'm asking whether they have ever
24 been willing to write into the indication that

1 there should be -- or any prescribing guidance
2 that there should be a requirement of improved
3 function.

4 A. I'd have to go back and just check
5 the record. I'm not sure.

6 Q. Okay. You mentioned a couple of
7 times, when you were talking about Dr. Woodcock
8 in particular, but I think -- I think
9 generally -- and you'll tell me if what I'm
10 saying is fair or not -- you talked about the
11 FDA trying to strike a balance.

12 And if I hear your testimony right,
13 it sounds to me like what you're saying is
14 the -- as you read the record, the FDA was
15 trying to strike a balance between what was
16 concerns about abuse and misuse and also
17 providing therapy for pain patients who may
18 need the therapy and benefit from it.

19 MR. RAFFERTY: Object to the form.

20 A. Yeah, I think the FDA was -- I
21 think the FDA was overwhelmed.

22 Q. You can't answer the question of
23 whether they were trying to strike the -- if
24 you don't know, just tell me you don't know.

1 A. I know. I mean, these are -- I
2 mean, I know. I think FDA was just
3 overwhelmed.

4 Q. Where is the evidence of that, sir?

5 A. The epidemic, ma'am.

6 Q. So the fact that things -- there is
7 a problem of abuse and misuse is proof that the
8 FDA was overwhelmed?

9 MR. RAFFERTY: Object to the form.

10 A. There is this graph, I guess
11 from -- is it Cuyahoga, right. And I'll just
12 take it, and we can just see if I can do this.

13 Q. Sir, I'm going to ask you to answer
14 my question. I just want to know if --

15 A. Well, I am.

16 So there is this graph, right.
17 Everyone's seen it. It's Cuyahoga Department
18 of Health. And it says, Prescription drugs led
19 to a larger overdose epidemic than illicit
20 drugs ever have, right. And it shows the
21 graph, right.

22 And I think FDA goes back and looks
23 at this -- and I know it -- and goes, how did
24 this happen?

1 Q. That's not my question.

2 A. And I think -- I think
3 it's over- --

4 Q. Sir --

5 A. I think that they are --

6 Q. I don't usually move to strike, but
7 this is not anywhere in the realm of my
8 question. It's not even close. So we're going
9 to -- we're going to go back to my question.

10 A. Okay.

11 Q. From your review of the record --
12 you've talked about balance -- what is the
13 balance that was trying to be struck?

14 A. So the FDA, you know, did -- tried
15 to, I think, repeatedly -- 1996, don't use this
16 for step two; 2001, restrict, narrow the
17 indication; REMS -- risk maps; REMS. It's
18 trying to bring under control, by the tools
19 that it had, this -- this part of the curve
20 from prescription drugs. And it can't do it.

21 Q. So my question again is, what --
22 the balance that you've said was trying to be
23 struck, would you agree with me, in part, was a
24 balance of trying to ensure that these

1 medicines were available for patients who
2 needed them and benefitted from them and trying
3 to limit or reduce rates of abuse and misuse?

4 A. Right, the addiction that was going
5 on --

6 Q. Okay.

7 A. -- in this country. I think that's
8 a -- that's probably a fair statement.

9 Q. Okay. And the balance -- there
10 were people who felt very strongly over time on
11 both sides of that discussion, correct?

12 MR. RAFFERTY: Object to the form.

13 A. No, I don't think people are on,
14 quote -- well, I don't know which people you're
15 talking about. I don't think people are on
16 different -- different sides of this.

17 Q. Well, let me -- let me --

18 A. I'm not sure I understand that.

19 Q. Let me rephrase that. Nobody's in
20 favor of abuse or misuse, of course, and
21 nobody's in favor of people suffering.

22 But would it be fair to say that
23 there have been multiple opportunities over the
24 years when the FDA has opened this issue for

1 public comments and heard from different
2 stakeholder groups? Yes?

3 MR. RAFFERTY: Object to the form.

4 A. A lot of that contrived.

5 Q. Are you -- do you have evidence
6 that pain patients who came and spoke to the
7 FDA about the importance of their medicine,
8 that that was contrived?

9 A. I certainly see significant
10 campaigns done by organizations that have been
11 funded by your companies that lobbied very
12 extensively that -- the mantra was --

13 Q. Sir --

14 MR. RAFFERTY: No --

15 MS. FREIWALD: No. I asked a
16 question about the AdCom.

17 MR. RAFFERTY: No. This is in
18 direct response to the question.

19 Q. I asked the question about at
20 public hearings.

21 Are you testifying that anybody who
22 came and spoke at a public hearing where
23 conflicts of interest were expressed,
24 including, particularly, pain patients, that

1 their testimony was contrived --

2 MR. RAFFERTY: Well, objection.

3 Q. -- and that you know that for a
4 fact?

5 MR. RAFFERTY: Objection.

6 Q. And you're testifying under oath.

7 MR. RAFFERTY: Objection.

8 Are you asking about particular
9 patients or anybody? Because you --

10 MS. FREIWALD: Well, I started out
11 with the patients. That's actually what
12 I asked --

13 MR. RAFFERTY: Well, you asked both
14 in this question, anybody that spoke and
15 then patients.

16 Q. Are you asking -- are you -- are
17 you testifying that you have evidence that
18 you're prepared to give under oath that
19 statements made at public hearings by pain
20 patients were contrived?

21 A. I'd have to go back and look at the
22 record to that.

23 I certainly see letters that were
24 written by companies or facilitated by

1 companies to doctors to get them to -- to
2 limit -- limit restrictions.

3 Q. Sir, I could not be more clear.
4 I'm asking about at public hearings, advisory
5 committees, people who got up and told their
6 personal stories and asked to not have their
7 medicines limited. Are you saying that those
8 statements were contrived?

9 A. I am not saying that, but I am --

10 Q. Okay. That's all I -- that's all I
11 want to know.

12 A. Well, you're cutting me off, but --

13 Q. That was my only question.

14 A. But you cut me off.

15 Q. Are you testifying that there were
16 any AdComs where people were supposed to
17 disclose conflicts of interest and you know
18 that they did not?

19 A. I didn't -- I did not have any
20 opinion on that in my report --

21 Q. And are you aware that non- --

22 A. -- but I can look at that.

23 Q. Okay.

24 A. I mean, I just haven't had time to

1 go look at that, but I'd be happy to look at
2 that.

3 Q. And am I correct that at these
4 Advisory Committee hearings, when people have
5 to disclose their conflicts of interest, they
6 only have to disclose them if they've gotten
7 money from pharmaceutical companies or other
8 corporate entities that might have a stake in
9 this? Correct?

10 A. You'd have to -- we'd have to have
11 the rules. They are complex, the waivers, and
12 what the disclosures have to be, and there's
13 been controversies of what exactly has to be
14 done over the years.

15 Q. So I mean, just for example, if
16 somebody got up in an AdCom and spoke, they
17 wouldn't have to disclose that they've been a
18 paid expert for plaintiffs' lawyers in opioid
19 litigation?

20 A. I -- let's look at the regs, and we
21 can -- and the rules and see what requires
22 disclosure.

23 Q. As the former Commissioner of the
24 FDA, do you know?

1 A. There's been a lot of controversy
2 about who can -- who has to disclose what.
3 It's not been as tight as it maybe should be,
4 and I'd want to have --

5 Again, if you're asking me exactly
6 what the rules are, I've not looked at them in
7 a while. I know that there are significant
8 controversies surrounding that. And again, I'm
9 happy to look at that.

10 Q. Have the rules changed over time?

11 A. Yes. I think that the rules have
12 changed somewhat, to my recollection. But
13 again, I've not studied that as part of this,
14 so I wouldn't want to testify without doing
15 some more homework on that. I'm happy to do
16 that.

17 Q. So sitting here today, just so
18 we're clear, you don't know if there is more
19 disclosure by people who may have commercial
20 ties and thus potentially those conflicts of
21 interest than people who have other kinds of
22 conflicts of interest? They've done work for
23 plaintiffs' lawyers in litigation, or they have
24 some kind of personal, quote, unquote, axe to

1 grind, or whatever it might be?

2 MR. RAFFERTY: Object to the form.

3 A. Yeah. Again, it's a pretty broad
4 question, and I'm not sure everything is of the
5 same -- the same -- I think these things pose
6 different parts of different issues.

7 Q. Have you offered -- if I understand
8 it, you've essentially taken the view in this
9 case that opioids are appropriate for cancer
10 pain and some acute pain.

11 Am I characterizing your view
12 correctly?

13 A. Do you want -- do you want to point
14 to the paragraph you're referring to?

15 Q. I was afraid you were going to ask
16 me to do that. Let me ask it this way.

17 Have you --

18 A. Hold on a second. I lost my mic.

19 Q. Okay.

20 A. But I didn't lose my clip.

21 MS. LEVY: While we're pausing for
22 a moment, can we get the court reporter
23 to tell us how much time --

24 MS. FREIWALD: Yeah.

1 MS. LEVY: -- we have used on the
2 record, please?

3 VIDEO OPERATOR: I need to go off
4 the record to do it.

5 MS. FREIWALD: Okay. We'll take a
6 break.

7 VIDEO OPERATOR: 3:33, we're off
8 the video record.

9 (Recess from 3:33 p.m. until
10 3:40 p.m.)

11 VIDEO OPERATOR: 3:40, we are on
12 the video record.

13 BY MS. FREIWALD:

14 Q. I'm going to ask the question a
15 little differently.

16 Are you going to offer an opinion
17 that any specific change to the indication for
18 ER opioids should have been made at any
19 particular period of time?

20 A. That's such a broad question. I
21 apologize. I'm just -- I'm going to answer the
22 question -- let me say this. I think my
23 opinions are either in the report or my answers
24 to this, so anything I say in the next two

1 days. So depending on how you phrase the
2 question, I don't want to say no --

3 I mean, obviously, there were
4 changes to the label. So I mean, further
5 changes to the label, are you asking, beyond --
6 depends what section of the label you're
7 asking.

8 Q. Indication.

9 A. For which drug?

10 Q. For ER opioid products.

11 A. You've got to be a little more
12 specific so I can be exact. If you want to
13 give me the actual opioids.

14 Q. Let me -- I'll ask you for
15 OxyContin.

16 A. Could we pull up the -- can I just
17 have the label in front of me, the existing
18 label in front of me?

19 Q. Well, let's go back --

20 A. So -- so -- so I can -- I just -- I
21 really want to answer your question, but I just
22 want to have the existing label, because we're
23 talking about a change to the label. I
24 apologize.

1 Q. Well, I'm not talking about just
2 from 2017 forward. I'm talking about --

3 I mean, I will represent to you
4 that the -- I think you actually represented to
5 me that the initial label was moderate to
6 severe pain for more than a few days, then it
7 was for an extended period of time, then there
8 were changes in 2013.

9 I just want to know globally -- and
10 I think the question would apply to most of the
11 extended-release products who had comparable
12 indication -- whether you're expecting to offer
13 an opinion that that language should have been
14 changed in some particular way at some prior
15 point in time.

16 A. So given how the drug was going to
17 be marketed -- given how the drug was marketed,
18 right, I think the label should have been
19 changed, right.

20 Q. To say what?

21 A. I think that certainly closer --
22 for example, in 2001 -- certainly closer to
23 2017, and then we can discuss whether 2017 is
24 adequate.

1 But I think given how the drug was
2 marketed, making those changes in 2017 and
3 2001, as a follow-up to that meeting, would
4 have been appropriate.

5 Q. And is that an opinion that you've
6 ever offered at any point in time before
7 litigation?

8 MR. RAFFERTY: Object to the form.

9 A. You'd have to -- opinion? I don't
10 think I've testified before. I mean, you'd
11 have to go back and look. I mean, I'd have to
12 refresh what I've said, I mean, in all -- in
13 all statements. So I'm not -- I haven't given
14 opinions before this.

15 Q. And have you done anything to test
16 whether -- had the label in 2017 existed in,
17 let's say, 2001, that events would have turned
18 out differently?

19 MR. RAFFERTY: Object to the form.

20 A. Yeah, I think that had the label --
21 well, it would depend on your client's conduct,
22 and so I couldn't predict that.

23 But I think that the 2017 label,
24 again, and not allowing -- being clearer about,

1 for example, alternatives and using other drugs
2 first and when not to use this would have
3 reduced -- could have reduced the marketing
4 practices and would have -- and would have
5 changed the number of drugs in interstate
6 commerce.

7 Q. So do you have any methodology to
8 test that?

9 A. Yeah. So if you look at the
10 company documents, there are -- there are --
11 there are documents that talk about
12 specifically return on investment by
13 promotional -- you're moving your head -- I
14 mean, that --

15 Q. My question is, do you have any
16 methodology to test the notion that the 2017
17 label, if implemented in 2001, would have
18 avoided a problem of abuse and misuse?

19 A. So we -- so we do see in
20 documents -- I'm happy to go through them --
21 that there were on -- because of certain
22 promotional activities -- or we can discuss
23 whether they were allowed in because of the
24 label -- did result in specific increases in

1 prescription numbers.

2 Q. That's not my question. My
3 question --

4 A. That's the methodology.

5 MR. RAFFERTY: Objection. That is
6 exactly your question.

7 MS. FREIWALD: No.

8 Q. The question is --

9 MR. RAFFERTY: He just explained
10 his methodology.

11 Q. -- is there a methodology to test
12 how something almost 20 years later would have
13 done what you say it would have done?

14 A. We do know -- for example, what we
15 can do is say, had promotional activities been
16 different --

17 Q. I didn't ask you about promotional
18 activities --

19 A. Well, but --

20 Q. -- I asked you about the label.

21 A. Well, but a label -- that's what --
22 you know, the label would have, hopefully -- if
23 your companies would have followed, then it
24 would have limited some promotional activities

1 which we do know increased number of
2 prescriptions.

3 Q. Okay. You haven't done any kind of
4 analysis of how much the 2017 label would have
5 affected events going back to 2001? I mean,
6 you haven't done some regression analysis or
7 anything like that?

8 A. No. But we do know, for example,
9 that the CDC guidelines -- there are documents
10 that that -- that translate --

11 I'll let you get --

12 Q. I'm listening.

13 A. We do know there are documents --
14 and I'm happy to show you -- where companies
15 have done an analysis of the CDC guidelines and
16 what that would translate into money lost if
17 those were followed.

18 Q. Okay. Other than that, my question
19 is, have you done any kind of a regression
20 analysis or anything --

21 A. No.

22 Q. -- that some other person could
23 follow the methodology and say, this is what
24 you did?

1 A. I reviewed the companies' analyses
2 that do that and look at what the increase in
3 prescriptions were.

4 Q. And so is it your testimony that
5 the 2017 label is an appropriate label?

6 A. No, I didn't say that. I said if
7 you'd give it to me, I'm happy to discuss it
8 with you. I think it's certainly improved from
9 the 2001 label --

10 Again, which companies' labels? We
11 just have to be careful.

12 Q. Okay.

13 A. I don't want to be talking in the
14 abstract.

15 Q. Okay. Do you agree that chronic
16 pain is a serious medical condition?

17 A. I believe the diseases -- the
18 underlying diseases that may result in pain
19 over a long term are an important medical
20 condition.

21 Q. You don't believe that the pain
22 itself is an important medical condition?

23 A. I think -- again, that's a slogan
24 that got us into some trouble in phrasing it

1 like that.

2 Q. Do you think pain is not a real --

3 A. I didn't say that --

4 Q. -- problem?

5 A. I didn't say that at all. I think
6 pain is a very significant problem, okay? But
7 I do think that when one talks about pain, one
8 has to recognize that that pain arrives from
9 certain places, and those underlying conditions
10 are the cause of -- just to focus on the
11 pain -- one should focus on the causes of those
12 pain.

13 Q. Well --

14 A. But I certainly am strongly, you
15 know -- my whole life, you want to reduce pain
16 and suffering. There's no question. But the
17 way to do that is to treat the cause and the
18 etiology of that pain.

19 Q. That may not be true, right?

20 A. Of course.

21 Q. You may be treating the cancer, and
22 somebody may go on and live forever with
23 chronic pain, even though their cancer is under
24 control.

1 You may have an amputee, and they
2 function well with a prosthetic, but they have
3 chronic pain.

4 You may have somebody who has
5 sickle cell disease, and they manage their
6 disease, but they have chronic pain.

7 MR. RAFFERTY: Is there a question?

8 Q. So your statement --

9 A. I disagree --

10 Q. -- is not true, right?

11 MR. RAFFERTY: Objection.

12 A. No. There is an underlying
13 pathophysiology. I'm happy to discuss it in
14 each one of those instances of what the
15 underlying pathophysiology is that's causing
16 that pain.

17 Q. So do you --

18 A. If you --

19 Q. I just have a question.

20 MR. RAFFERTY: No, no, no. Do not
21 interrupt him.

22 A. That's fine. Go ahead.

23 Q. Do you believe there shouldn't be
24 pain medications unless they treat an

1 underlying disease?

2 MR. RAFFERTY: Objection, misstates
3 his testimony.

4 A. That's not what I said at all.

5 Understand, I allowed certain pain
6 medicines to continue after there was
7 considerable pressure to limit them. So I
8 certainly do.

9 But I believe what's important,
10 right, I mean, is the statement that -- I mean,
11 pain -- pain certainly needs to be attended to,
12 but the appropriate treatment of chronic pain
13 is to treat the underlying conditions.

14 Q. And sometimes you may need to just
15 treat the pain as well, or do you not recognize
16 that?

17 A. I think treating the pain without
18 looking for the underlying conditions would be
19 reckless.

20 Q. Okay. So your testimony is that
21 you don't think it's appropriate to have
22 treatment for pain even if the underlying
23 condition can't be fully treated?

24 MR. RAFFERTY: Object to the form.

1 Misstates his testimony.

2 A. No.

3 Q. Okay.

4 A. I've spent my life trying -- I
5 mean, I think you have to try to treat the
6 underlying condition and the cause of that
7 pain. I think that's the goal.

8 You certainly can concomitantly
9 treat the pain, but to treat the pain without
10 treating the underlying condition would be --
11 would be wrong. And I don't --

12 Q. Nobody is saying you shouldn't
13 treat somebody for an underlying condition.

14 A. Sure.

15 Q. But you would agree that pain may
16 be something that needs to be treated with a --
17 some kind of a medicine that isn't necessarily
18 for the treatment of the underlying condition;
19 it's for the treatment of the pain?

20 A. Again, we've just spent the last
21 half hour talking about what the indications
22 should be. So just say, treat the pain -- I
23 mean, it's more complicated than that. Of
24 course, you want to treat pain. I'm saying

1 that your statement was a simplification of, I
2 think, what responsible medicine would be.

3 Q. I didn't ask about responsible
4 medicine generally or what you -- of course,
5 you treat a cancer patient for their cancer,
6 but -- you treat any number of diseases for the
7 underlying disease condition. I wasn't getting
8 into that.

9 But you don't disagree with the
10 notion that pain should be addressed? If it
11 can be addressed by curing the disease, great.
12 But if it can't, there's a need for pain
13 therapy.

14 MR. RAFFERTY: Object to the form.

15 A. Sure. But you also have to
16 address -- you have to recognize that it's not
17 just treating the pain. It's treating the
18 underlying condition --

19 Q. Sure.

20 A. -- which is what's -- which is
21 absolutely critical.

22 Q. Sure.

23 And would you agree that all
24 medications for the treatment of pain have some

1 risks?

2 A. Sure.

3 Q. And do you know how many people die
4 of GI bleeds every year?

5 A. From what cause?

6 Q. From NSAIDs.

7 A. I don't have it at the top of my
8 head.

9 Q. Okay. And do you know how many
10 people die of hepatic failure from Tylenol?

11 A. From overdose -- the number of
12 overdoses? I can look it up and get it to you
13 during the break if you really want to know.

14 Q. In doing your report, did you do a
15 review of statements pre-1996 with regard to
16 the treatment of pain being important for good
17 medical care, a fundamental human right,
18 anything like that?

19 MR. RAFFERTY: Object to the form.

20 A. Again, I looked pretty extensively
21 at the record of doctors and what they were
22 saying about pain.

23 Q. And would you agree with me that
24 the record of doctors and medical societies

1 reflects that those kinds of statements about
2 the need to treat pain or shortcomings in
3 medical treatment with regard to pain precede
4 1996?

5 MR. RAFFERTY: Object to the form.

6 A. Yes. I think that would be a fair
7 statement. It's -- and I try to sort this out.
8 It's -- well, yes, let me leave the question --

9 Q. Okay.

10 A. -- leave the answer. There are
11 statements about treating pain.

12 What was pharmaceutical companies
13 and what were doctors and -- sorting that out
14 is a little hard to do, because there's not
15 really a full record there.

16 Q. But they precede 1996? They go
17 back?

18 A. Certainly, MS Contin and other
19 drugs go back. We talked about Haddox. We
20 talked about -- I looked at the record. I've
21 looked at the APS speeches. I've looked at --
22 I've looked at the record, yes.

23 Q. And other societies -- the Montreal
24 IASP, did you look at that?

1 A. I've looked at IASP. I've studied
2 JCAHO. I have studied a number of different --
3 tried to understand the interconnections.

4 And again, the record, when you go
5 back, is a little skimpy back into the '80s.

6 Q. But fair to say there are
7 statements about increased importance of
8 treating pain that go back into the '80s and
9 early '90s, correct?

10 A. Yeah. I think that -- I think
11 that's correct. I think where it gets
12 confluted -- where there's a switch is where
13 that statement becomes associated, "and use
14 opioids." I think that was -- that's the
15 issue.

16 Q. And there are statements going back
17 prior -- into the '80s and early '90s about
18 doctors being too concerned to prescribe
19 opioids. There were surveys done and concerns
20 raised at -- by state medical boards about
21 doctors' fears of treating opioids [sic] and
22 not -- not responding to patients enough?

23 MR. RAFFERTY: Object to the form.

24 A. The record shows that your company

1 did those surveys and recognized that the fear
2 of addiction needed to be overcome to use those
3 drugs.

4 Q. That wasn't my question, sir.

5 I'm asking, going back into the
6 early '90s, that surveys were done that had
7 nothing to do with any pharmaceutical company
8 that looked at fears among doctors in
9 prescribing drugs.

10 A. I've seen certain articles or
11 speeches that discuss, but the surveys that I
12 see about -- the specific surveys I see in the
13 record that I was given were done by your
14 company.

15 Q. What survey is that?

16 A. I have a whole -- there's a whole
17 bunch of basically focus groups through the
18 1990s that led up to the introduction of
19 OxyContin and the fear of addiction and how
20 that needed to be overcome.

21 Q. What published survey are you
22 referring to, if you can tell me, that was,
23 quote, unquote, done by my company prior to
24 1996?

1 A. They were all proprietary, I
2 believe, but there were a whole host of focus
3 groups that your company did.

4 Q. I'm not talking about advisory
5 boards internal once the product was on the
6 market. I'm talking about published studies,
7 surveys that you're saying were funded or done
8 by my company.

9 A. Your company -- I mean, your
10 company did surveys of doctors and focus groups
11 to understand the impediments and barriers to
12 publication -- to prescribing. Sorry.

13 Q. When you say, my company, what
14 is -- are you representing that you have
15 evidence that they were sponsored with
16 unrestricted educational grants, or are you
17 saying that they were -- you somehow have
18 evidence -- because it's not in the report --
19 that there were Purdue-done surveys?

20 A. Your company did a whole bunch of
21 focus groups of doctors -- having third parties
22 do those surveys -- to recognize that addiction
23 was a key element and a barrier to
24 prescription.

1 Q. Is that in your report somewhere?

2 A. I'd have to -- the report is 350
3 pages and the reliance list. I have seen those
4 documents, and you're asking me a question. I
5 have seen those surveys.

6 Q. I'm asking a really important
7 question. You're making a very sweeping
8 statement, and I didn't see that anywhere in
9 your report.

10 A. I'd have to go back and check.

11 Q. So I'm going to ask you on a break
12 if you have in your reliance materials evidence
13 of a Purdue-done survey --

14 A. I might be able to get it on break.
15 I'll be happy to see if I can get it to you by
16 tomorrow morning.

17 Q. -- pre-1996.

18 A. I'd have to go check on the date,
19 but there are -- just go into the database and
20 type in "surveys" and "addiction." There are
21 three or four that are right there in the
22 database.

23 Q. And that were published and --

24 A. No.

1 Q. Okay. That were published --

2 A. No. That were proprietary.

3 Q. Okay. I'm not asking about
4 whatever internal. I'm asking that were put
5 out and part of the medical literature.

6 A. No. This was -- this was privately
7 done surveys by your company to decide how to
8 position the company --

9 Q. Ah, okay.

10 A. -- to position the product.

11 Q. So you're talking about marketing
12 information that was --

13 A. Those are surveys to doctors.

14 Q. -- that was done to understand
15 doctors' thinking on the issue of prescribing.

16 A. I thought --

17 Q. Okay.

18 A. -- that's what you were talking
19 about.

20 Q. No, that's not what I'm talking
21 about.

22 I'm talking about surveys that were
23 done not associated with any company that
24 became published that looked at doctors'

1 concerns about prosecution, fear of prescribing
2 opioids even to cancer patients. Are you
3 familiar with those?

4 A. I know some of the UW work that was
5 done on that subject back in the early 1990s.

6 Q. Okay. Now, in terms of preparing
7 your report, there were a bunch of things I
8 didn't see, and I want to just confirm that I'm
9 right on this.

10 Does not look like you cited the
11 Senate hearings from 2001. Is that something
12 that you reviewed in terms --

13 MR. RAFFERTY: Object.

14 Q. -- of what was known at the time
15 about abuse and misuse of prescription opioids?

16 A. I'd have to go back and -- again,
17 my reliance list -- I'm familiar with that.
18 I'm familiar with Grassley, I mean, and number
19 of the committees that did work and some of the
20 Senate staff. And I think I've looked at that.
21 I'd have to double-check my reliance list.

22 Q. So I mean, just to be -- so you and
23 I are on the same page, one of the things I
24 hear you saying -- correct me if I'm wrong --

1 is that the FDA didn't have a full enough
2 appreciation of the potential for misuse or
3 abuse of prescription opioids and therefore
4 didn't do as much as they might have. That
5 seems to me to be one of yours opinions.

6 MR. RAFFERTY: Object to the form.

7 A. No. Can I -- can I put it in my
8 words?

9 Q. Sure.

10 A. So I think that in 1994, I can talk
11 firsthand, right.

12 Q. I want it succinctly, because we
13 have very limited time here. So --

14 A. I understand. Very succinctly.

15 MR. RAFFERTY: But answer the
16 question in your own words.

17 A. In 1994, right, when I worked --
18 when the agency and I narrowed the
19 indication -- or strengthened the indication in
20 the label of one of the opioid products, right,
21 it would be the farthest thing from my mind to
22 have thought the company would, five years
23 later or so, go expand the market to chronic
24 back pain and osteoarthritis.

1 If I had any idea, right, that that
2 was the intended population and they would try
3 to drive a truck through that indication,
4 right, I mean, I -- I'm not sure I would have
5 shut down the product entirely, because again,
6 I'm not in favor of that, but I would have
7 called them in and said, what in the world are
8 you thinking?

9 Q. Okay. My question is -- I
10 appreciate that. My question is a little
11 different.

12 Are you offering an opinion that at
13 no time between 1994 and 2017 or '18 or '19 did
14 the FDA understand how -- the patient types to
15 which the products were being marketed? It's a
16 very specific question.

17 MR. RAFFERTY: It's a -- objection.
18 It's a very broad question.

19 Q. I just want to know, are you -- is
20 it your testimony that at no time between 1994
21 and basically present, the FDA understood the
22 patient types to which the products were being
23 marketed?

24 MR. RAFFERTY: Same objection.

1 A. "He didn't seem to believe me that
2 OxyContin had no buzz. Will try on some
3 junkies."

4 Q. Sir --

5 A. The FDA had no --

6 Q. Sir, I'm going to --

7 A. The FDA had no sense of that
8 patient type that -- that it was being sold to.

9 Q. Okay.

10 A. "Stating that he agrees with using
11 oxy for PRN and chronic pain."

12 Q. Sir --

13 A. FDA had no understanding that your
14 company was marketing for that.

15 Q. Sir, you said to osteoarthritis
16 patients, to patients who had all kinds of
17 disease states.

18 MR. RAFFERTY: Once again --

19 Q. That's what you --

20 MR. RAFFERTY: Let the record
21 reflect that once again counsel is
22 interrupting him when she asked a very
23 broad question about what the entire FDA
24 knew over the -- from 1997 until today

1 about the patient populations.

2 The doctor is answering your
3 question, and then you interrupt him.
4 That's exactly what's been going on all
5 day.

6 A. "Using it in lower doses for milder
7 pain."

8 Q. Okay.

9 A. I don't think the FDA to this day,
10 right --

11 If you take these call notes, 1996,
12 1997, right, in different ERs -- "Oxy has a
13 street value," dated 1996.

14 Q. Sir --

15 A. I don't think FDA has an
16 understanding. Your company has stated that it
17 did not know about the street value of oxy
18 until 2000, 2001.

19 Q. Sir --

20 A. This is 1996. I don't think FDA
21 has a complete picture to this day.

22 Q. Sir, did you review the Senate
23 hearings in 2001 to know what was discussed
24 about abuse and misuse?

1 A. I'd have to go back and look
2 specifically about that.

3 Q. Okay.

4 A. I believe I've looked at those.

5 Q. Did you look at the AdComs from the
6 early 2000s?

7 A. Yes.

8 Q. And would you agree with me that
9 abuse and misuse was discussed?

10 A. Yes. And I also -- yes. And there
11 were statements made of when this was known.

12 Q. Okay.

13 A. Okay? 1996 -- there was no
14 statement made that your company knew back to
15 1996.

16 Q. So we can -- and would you agree
17 with me that there were public meetings held in
18 many years between -- 2002, '03, where issues
19 of abuse and misuse were discussed?

20 A. Absolutely.

21 Q. Okay.

22 A. And that's where the agency's
23 overwhelmed, because the ground has been set,
24 right. The change in medicine, as your client

1 said, was made already by that time. By 2001,
2 you changed the practice of medicine.

3 Q. And there was an IOM report in
4 2010?

5 A. Yes.

6 Q. And there were AdComs discussing
7 the REMS in 2010?

8 A. Yes, which -- and again, let's just
9 put a footnote there, because you said that the
10 REMS give FDA authority over marketing and
11 promotion, and there is nothing in the statute
12 that does that. I went back at break and
13 checked on that.

14 Q. And the -- there were citizens'
15 petitions at various times?

16 A. Yes.

17 Q. Okay. And there were discussions
18 about PDMPs and nationalizing PDMPs?

19 A. There were certainly discussions
20 about that.

21 Q. Okay. And the FDA had discussions
22 with the DEA?

23 A. FDA --

24 MR. RAFFERTY: Object to the form.

1 A. -- has discussions with DEA, I
2 would say, regularly. I mean --

3 Q. And all of those discussions
4 included questions about whether -- what was
5 driving abuse and misuse, whether it was
6 prescribed patients, diversion, drug cartels --

7 MR. RAFFERTY: Objection.

8 Q. -- some combination?

9 A. I think that there -- you know,
10 again, I think the generally accepted fact,
11 right, is that a significant portion --
12 certainly in Ohio and others -- got started on
13 prescription drugs, and there were different
14 phases of the epidemic.

15 Q. That really wasn't my question.

16 My question was that all these
17 public meetings -- that at all these public
18 meetings, there were discussions at various
19 times about abuse, misuse, what was coming from
20 properly prescribed patients, what was the
21 result of doctors not handling patients
22 correctly, what was the result of abuse, of
23 diversion, what was the result of cartels.
24 Those were all parts of public discussions --

1 MR. RAFFERTY: Object to the form.

2 Q. -- correct?

3 A. There were many public discussions.

4 Q. Okay. Now, with regard to

5 Purdue --

6 A. We're on Purdue-specific?

7 Q. -- you have cited in your report a
8 whole bunch of call notes and other statements.

9 Is there anything that you looked
10 at post-2003 or so that is informing your
11 opinions in your report?

12 A. Yes.

13 Q. Where -- where are the post-2003 or
14 so call notes in your report?

15 A. There are PowerPoint --

16 MR. RAFFERTY: Object to the form.

17 A. Sorry, sorry. You asked me whether
18 there's 2000- -- just -- are you talking
19 about -- just about call notes?

20 Q. Yeah. Let's start off with all
21 the -- you have call notes in your report.

22 I --

23 A. Call notes got scrubbed at a
24 certain point in time. The industry stopped

1 putting down, because of the things that I just
2 read you. That changed as an industry practice
3 in general.

4 If you want to go where -- the
5 2011, 2012, 2013, the increase -- the continued
6 search for increased ROI, to increase target,
7 there are PowerPoint slides of your company
8 about the promotionally sensitive nature of
9 their detailing of oxy, even when this epidemic
10 is in full bloom.

11 Q. So I'm going to stop you for a
12 second.

13 Did you actually look at any
14 post-2003 call notes to see what they look like
15 for Purdue?

16 MR. RAFFERTY: Doctor, this isn't a
17 memory test. You can look at your
18 report if you want to.

19 A. Yeah, I mean, I --

20 MR. RAFFERTY: You can go
21 through the --

22 A. I looked at -- I looked at a lot of
23 call notes. I'd have to refresh exactly the
24 cohort that I looked at. I probably looked at

1 thousands of call notes.

2 Q. Do you know what the structure or
3 nature of call notes, sitting here today, with
4 Purdue was post-2006, '07 on?

5 A. I can tell you that --

6 Q. I want Purdue-specific; I don't
7 want an industry-general answer.

8 A. I'd have to go back and -- I'd have
9 to go back and look specifically. The format
10 depends on what -- what I see is different
11 formats, because I've run those formats by
12 different regions of the country. They are not
13 exactly the same.

14 Q. Do you know what Purdue did with
15 regard to sales force monitoring and sales
16 force training from 2007 forward?

17 A. I looked at some of the field --
18 some of the field reports that -- and the
19 ride-alongs. I looked at some of them.

20 Q. Did you look at all of the changes
21 in SOPs --

22 A. You were --

23 Q. -- or other programs?

24 A. You had just pleaded guilty, I

1 mean, to a criminal charge, so yes, I'm aware
2 of that. And --

3 Q. Where are they cited in your
4 report?

5 MR. RAFFERTY: Don't -- please stop
6 interrupting the witness, Ms. Freiwald.

7 A. What is?

8 Q. My question was, did you look at
9 these SOPs?

10 I'm not asking if you were aware
11 that there was a guilty plea. I'm asking,
12 where in your report do you reference changes
13 that were made in practices and procedures from
14 2007 forward with regard to sales activities?

15 A. I'm not sure I do. I have to go --
16 well, I certainly look at the -- what I do
17 reference in the report is actual sales
18 activities, I mean, done corporately. And
19 those are in the report certainly for 2011,
20 2012, and 2013, and the detailing in those
21 PowerPoint presentations.

22 Q. There's -- I did not see anything
23 discussing actual calls to doctors in your
24 report -- I might have missed one, but -- in

1 the post-2003 time period.

2 A. So what --

3 Q. Does that sound right to you?

4 MR. RAFFERTY: Object to the form.

5 A. No, because -- well, we may be
6 saying the same thing.

7 If you look at these PowerPoint
8 presentations in 2011, 2012, 2013, of that ilk,
9 it talks about detailing and the promotionally
10 sensitive nature and how there could be an
11 increased number -- return on that investment.

12 And that data is at the aggregate
13 level at that time. That's not based on call
14 notes. That's based on your company's -- your
15 client's own analysis.

16 Q. I want an answer to my question.

17 Is there -- did you do -- do you
18 have anything in your report where you were
19 looking at what was actually reflected in calls
20 to doctors in the post-2007 time period that
21 you can remember?

22 MR. RAFFERTY: Object to the form.

23 Asked and answered.

24 A. I remember looking at PowerPoints

1 post-2007.

2 Q. Not call notes?

3 A. After about a thousand call notes,
4 I stopped looking at call notes.

5 Q. Okay. So the record will -- if you
6 looked at them in any detail, you would -- if
7 they're not in your report, they're not in your
8 report, right?

9 MR. RAFFERTY: Object to the form.

10 A. Well, there's also my schedules,
11 because -- the schedules have appendices and
12 have a lot of call notes in them.

13 What's sitting here in top of my
14 head, I mean, are that later activity is
15 reflected in the companies' strategic plans
16 and, in essence, their marketing plans. That's
17 where -- and that was focused on, in essence,
18 calls to doctors.

19 Q. Okay. But just, please, to answer
20 my question, when you're looking at call notes,
21 you're looking at that early period before
22 2007?

23 MR. RAFFERTY: Object to the form.

24 A. I have to go back and look -- let

1 me just search my report. Let me search my
2 schedule. So I don't take time --

3 Q. Okay. You can do that when we're
4 on a time break.

5 A. Time break, and let me get back to
6 you exactly what the call notes --

7 Let me just say that I did ask
8 repeatedly for call notes, and I was getting --
9 I didn't get everything that I had asked for,
10 because I don't -- I think there were
11 tug-of-wars on what was produced.

12 Q. Okay. Is there any ad campaign,
13 specific ad campaign, that you take issue with
14 as -- that Purdue had that is contrary to the
15 label from 2007 forward?

16 A. Ad campaign? I'd have to go back
17 and check. I just -- I don't recall.

18 Q. Is there any ad --

19 A. I mean, I --

20 Q. Okay. Is there any ad campaign or
21 detail piece that you say should have been
22 submitted to FDA, pursuant to a 2253 or
23 otherwise, and was not from 2007 forward?

24 A. Yeah, I think that the issue is

1 not -- well, the issue is not what's submitted.
2 The issue is what's reviewed and what's brought
3 to the agency. I give your -- you know, a lot
4 of materials --

5 Q. I just --

6 A. -- were submitted.

7 Q. Okay. Did you find anything that
8 should have been that wasn't submitted?

9 A. I'd have to -- sitting here, I
10 don't have a recollection of specific ad
11 campaigns at that --

12 Q. Okay.

13 A. -- that date.

14 I do have a recollection of this
15 increase in detailing that was promotionally
16 sensitive, increased the amount of sales.

17 Q. Is there any particular sales
18 message from 2007 forward that is reflected in
19 any kind of detail aid that you are going to
20 testify was inconsistent with the approved
21 labeling?

22 A. If it's not in my report -- I'm
23 going to stick to my report.

24 Q. Okay. Now, you knew Curtis Wright

1 when he was -- when you were both at FDA?

2 A. Yes.

3 Q. Did you consider him a good
4 reviewer?

5 A. I didn't know Curtis in that
6 capacity.

7 Q. In what capacity did you know him?

8 A. I knew Curtis because he dealt with
9 the psychotropic medications. I asked Curtis
10 to help me on tobacco. So it was in that
11 context that I intimately associated with
12 Curtis.

13 Q. Did he do a conscientious job in
14 that work?

15 A. I find to be a -- at FDA -- I mean,
16 he -- "conscientious" would probably not be the
17 adjective I would use.

18 I think -- I found him a decent --
19 a decent, thoughtful fellow, who -- not that I
20 would agree with him on everything, but who had
21 certain insights. And I found him to be a --
22 you know, a decent guy and, actually, a very
23 nice guy and an interesting guy.

24 Q. I'm going to take a wild guess and

1 say that you probably didn't agree with
2 anybody -- with everybody at FDA on -- I said
3 that badly.

4 There's probably nobody at FDA who
5 you ever agreed with a hundred percent of the
6 time?

7 MR. RAFFERTY: Object to the form.

8 Q. That's a good thing, right?

9 So when you say you didn't agree
10 with Curtis a hundred percent of the time, that
11 probably isn't that different from other
12 people?

13 A. No, I don't mean that in a
14 disparaging way. I mean, but it's not -- I
15 just don't want the record to show that I
16 would -- that I agreed with him on everything.
17 Again, he showed up at my request at certain
18 meetings. He gave certain insights that I
19 thought were thoughtful.

20 Q. Okay. And from -- now, the NDA for
21 OxyContin was actually submitted while you were
22 still at FDA?

23 A. Correct.

24 Q. And were you aware of the

1 submission?

2 A. No.

3 Q. Were you -- did you know who was
4 assigned to the review team?

5 A. I knew nothing about -- I mean,
6 I've looked. There is -- there was -- I have
7 no memory -- I think I've even asked Curtis.
8 There's no recollection from anybody, and
9 people will -- I mean, have reminded me.

10 I mean, I was involved in
11 Duragesic.

12 Q. Okay. That's fine.

13 A. I was involved in Oralet. I was
14 not involved in oxy.

15 Q. And the decision to proceed as an
16 interactive NDA, that was the agency's; do you
17 know?

18 A. Boy, that goes back to, actually,
19 pre-me. That was the philosophy of the pilot
20 review division that under my watch got
21 changed. Janet changed it in about '95, '96.
22 But that interactive -- that NDA day was a Carl
23 Peck-John Harter special.

24 Q. Okay. It wasn't unique to

1 OxyContin or opioids; it was something that
2 existed as an approach of the FDA in some of --
3 at the time?

4 A. It was. I mean, there's a --
5 there's a little thesis, a mini-thesis at
6 Harvard, that talks about the pilot review
7 division.

8 I think it would be fair to say
9 that pilot review division was set up by Carl
10 Peck and John Harter as an experimental way to
11 be able to -- I mean, the agency was taking a
12 considerable amount of grief about how long
13 review times were --

14 Q. Okay.

15 A. -- et cetera, and it was
16 experimental in that regard.

17 Q. Okay. Fair to say the FDA often
18 takes grief about either taking too long or not
19 enough time?

20 A. You and I can agree on that.

21 Q. Okay. And that --

22 A. So it goes to the territory.

23 Q. It goes to the territory. So some
24 people will criticize you for being too slow in

1 approving drugs, and some people will criticize
2 the agency in being too fast?

3 A. And sometimes they're the same
4 person.

5 Q. And sometimes those criticisms are
6 all colored by hindsight?

7 A. That requires for editorial
8 comment, so I'm not going to.

9 Q. And in your dealings with Curtis
10 while you were at the agency and since, in your
11 review, I assume you have not seen anything
12 that suggests that he was not -- that he was
13 doing anything other than attempting to review
14 the NDA for OxyContin in a conscientious and
15 thorough way?

16 MR. RAFFERTY: Object to the form.

17 A. I want to be careful here in
18 answering that question. What I see -- what I
19 think I see -- I could be wrong on this, but
20 you're -- I mean, I'm addressing -- you're
21 asking, any -- do you really want to ask me
22 "anything"?

23 Q. I'm asking whether -- whether
24 you're going to offer an opinion that you have

1 some evidence that he didn't try to do a good
2 job.

3 A. No. I mean, there's some concerns
4 when you look -- I mean, you know, there are --
5 there are some concerns that I have. I'm not
6 going to -- my intent is not to blurt out an
7 opinion that's not in my report or put in --

8 But I think there's certain
9 questions just -- that I have, just because
10 you're asking me whether there's anything, but
11 I'm not planning to offer any opinion on that.

12 Q. Okay. And as you've -- did you
13 review the NDA for OxyContin beginning to end?

14 A. I probably spent -- I probably
15 drove counsel nuts trying to get the NDA, go
16 try to do that and get -- I have the entire
17 NDA -- but that, in itself, was a feat -- in
18 PDF format. I have all the volumes of the NDA.

19 I can tell you that I have reviewed
20 several volumes. I have not reviewed the
21 entire NDA. I'm not sure anybody has reviewed
22 the NDA.

23 MS. LEVY: So another way to say
24 that is "no."

1 MS. FREIWALD: Yeah --

2 MS. LEVY: I would request --

3 MR. RAFFERTY: Excuse me, Counsel.

4 MS. LEVY: I would like to place an
5 objection --

6 MR. RAFFERTY: Under the
7 protocol -- no. Under the protocol --

8 MS. LEVY: I request on the
9 record --

10 MR. RAFFERTY: No.

11 MS. LEVY: -- that the witness be
12 instructed to answer the question asked.
13 Again, we are well over five hours into
14 this transcript --

15 MR. RAFFERTY: That is not my --
16 that is not this witness's fault --

17 (Simultaneous speaking.)

18 MS. LEVY: We've got these long,
19 rambling answers --

20 MR. RAFFERTY: This is the way --
21 no. This is the way --

22 (Reporter interruption.)

23 MR. RAFFERTY: And under the
24 protocol, there is to be no speaking

1 objections or no colloquy from counsel.
2 And I'm sorry.

3 MS. LEVY: So Counsel --

4 MR. RAFFERTY: If you have an
5 issue, you can bring it up at the break,
6 but quite frankly --

7 MS. LEVY: I did. I did bring it
8 up at the break with you.

9 MR. RAFFERTY: -- the way this --
10 Let me finish, please.

11 The issue is the way the questions
12 are asked. He has been very responsive
13 to the questions. If you have an issue
14 with how the deposition is going, I
15 suggest you take it up on that side of
16 the V.

17 MS. LEVY: So I would like to make
18 a request on the record in the presence
19 of counsel and the witness that the
20 witness please try to do his best to
21 answer the questions that are asked as
22 succinctly as possible.

23 There are six, at least, and
24 possibly more, other defendants in this

1 matter that are entitled to time with
2 the witness, and so we would like for
3 this to move more quickly.

4 MR. RAFFERTY: That is -- and that
5 is a request made to --

6 MS. LEVY: So when there is a --
7 when there is a possibility of answering
8 a question with a simpler yes or no or I
9 don't know, we would request that you do
10 that.

11 THE WITNESS: And I'm most
12 respectful of that.

13 MS. LEVY: Thank you.

14 THE WITNESS: And I understand the
15 concern --

16 The question was, Did you review
17 the --

18 MS. LEVY: We don't need to review
19 the question.

20 THE WITNESS: Hold on a second.

21 MS. LEVY: That's a request for
22 going forward.

23 THE WITNESS: I understand.

24 But the questions was, Did you

1 review the NDA? If I answered that
2 "yes," it may give the impression that I
3 reviewed the whole thing. If I
4 answered -- I mean, so I have to
5 explain.

6 MS. FREIWALD: All you have to say
7 is, I reviewed some but not all.

8 MR. RAFFERTY: There is no
9 instructions by the defense lawyers on
10 how a witness answers a question,
11 period.

12 Now, continue with the questioning,
13 if you have more questions. We spent
14 six hours today talking about general
15 stuff. If there's an issue about
16 breaking up the time amongst defendants,
17 resolve it amongst yourselves.

18 BY MS. FREIWALD:

19 Q. Now, Doctor, you offer an
20 opinion --

21 I'm going to ask you if you would
22 just answer my questions. We'll try to move
23 through this quickly.

24 You offer an opinion as to -- that

1 the label -- that the promotion of the product
2 did not discuss the risk of tolerance and
3 dependence.

4 A. Could you just point me to the
5 page, please.

6 MS. FREIWALD: You know what?
7 Let's take a five-minute break, and then
8 we'll start.

9 VIDEO OPERATOR: 4:30, we're off
10 the video record.

11 (Recess from 4:30 p.m. until
12 4:54 p.m.)

13 VIDEO OPERATOR: 4:54, we are on
14 the video record.

15 BY MS. FREIWALD:

16 Q. Okay. So Doctor, we have very
17 limited time here, because I want to let the
18 lawyers for other companies ask questions, too,
19 so I'm going to try to see if we can do this as
20 efficiently as possible.

21 As I read your report with regard
22 to Purdue, you have an opinion on page 46 that
23 is, Purdue falsely marketed OxyContin as having
24 a lower potential for abuse as compared to

1 opioid -- as compared to other opioid products.

2 You have an opinion on 56 --

3 A. Excuse me. The first one was 46?

4 Q. Yeah.

5 MR. RAFFERTY: Do you have a
6 paragraph number? It might be easier.

7 MS. FREIWALD: It's the header.

8 MR. RAFFERTY: Oh, okay.

9 A. I'm sorry. I was reading 105. I
10 apologize. Okay. Thank you.

11 Q. Actually, that should be the second
12 one.

13 On page 40, you have an opinion,
14 Purdue's marketing misleadingly minimized the
15 similarities between OxyContin and morphine.

16 A. Yes, correct.

17 Q. And then on page 56, Header C is,
18 Purdue lacked substantial evidence regarding
19 the addictive potential of OxyContin, yet
20 misleadingly claimed that OxyContin was less
21 addictive than competitor opioid products.

22 And then on page 67, you have,
23 Purdue minimized the risks of tolerance and
24 physical dependence that patients could

1 experience with OxyContin.

2 And then on 73, you say, Purdue's
3 marketing minimized the risks of respiratory
4 depression, addiction, and abuse associated
5 with higher doses of OxyContin.

6 And then on page 80, you say, In
7 response to OxyContin not being effective for
8 12 hours, Purdue developed a strategy to
9 increase the total daily OxyContin dose but
10 failed to inform the public, putting patients
11 at risk.

12 And on page 94, you have, Purdue
13 promoted OxyContin for indications that were
14 broader than supported by substantial evidence
15 and for which safety and efficacy were not
16 established.

17 A. Correct.

18 Q. Okay? I'm not saying those are
19 your only opinions, but these seem to be the
20 majority of the headers that I saw, and I'm
21 going to see if we can kind of deal with them
22 in some relatively efficient manner.

23 So you have opinions as to morphine
24 equivalence, tolerance and dependence, risk of

1 addiction, pseudoaddiction, abuse.

2 (Exhibits Kessler-4 through
3 Kessler-7 marked for identification and
4 attached to the transcript.)

5 BY MS. FREIWALD:

6 Q. And I want to -- and I want to turn
7 your attention -- I've given you a bunch of
8 labels. Unfortunately, the numbering is not
9 quite in chron order.

10 Number 7 is the '96 label. That's
11 our mistake.

12 A. Right.

13 Q. And then Exhibit 4 is the 2001
14 label with the "Dear Healthcare Provider"
15 letter attached to it.

16 MR. RAFFERTY: Do you have extra
17 copies for counsel?

18 MS. FREIWALD: Yeah. We'll --

19 MR. RAFFERTY: Thank you.

20 MS. FREIWALD: I'll certainly put
21 them on the Elmo, too.

22 Q. 2005 is the 2014 letter -- I'm
23 sorry. Exhibit 5 is the 2014 letter, and
24 Exhibits -- I'm sorry. It's late in the day.

1 Exhibit 5 is the 2014 label --

2 A. Yes, ma'am.

3 Q. -- and Exhibit 6 is the 2018 label.

4 A. Correct.

5 Q. Okay. So, sir, turning to the '96
6 label --

7 A. Yes, ma'am.

8 Q. -- you would agree with me that
9 from the beginning, the label for OxyContin
10 contained a warning, "may be habit-forming,"
11 correct?

12 A. That's what the label said at that
13 time. It got moved into the abuse section.

14 Q. And there's also a note right here
15 at the top that it's a CII product, correct?

16 A. Correct.

17 Q. Okay. And that means it's a
18 Schedule II product with an abuse -- a high
19 potential for abuse?

20 A. Correct.

21 Q. And then the label also contained
22 language -- you seemed to be a little uncertain
23 about this when we talked before -- warning,
24 OxyContin tablets are to be swallowed whole and

1 not to be broken, chewed, or crushed. Taking
2 broken, chewed, or crushed OxyContin tablets
3 could lead to the rapid release and absorption
4 of a potentially toxic dose of OxyContin.

5 MR. RAFFERTY: Object to the form.
6 Move to strike the preamble.

7 A. I was fully aware of that.

8 The things I wasn't sure about was
9 the -- when you added on the elderly. That's
10 not in -- that was the question --

11 Q. Okay.

12 A. -- in my mind.

13 Q. So there's no dispute that there
14 was all-caps warning language from 1996 that if
15 the product was broken, chewed, or crushed, it
16 could lead to rapid release and absorption of a
17 potentially toxic dose of oxycodone?

18 A. That's what the label says.

19 Q. And similarly, there's no dispute
20 that there was language about tolerance and
21 physical dependence from the beginning in the
22 label, correct?

23 A. Correct.

24 Q. Tolerance is the need for

1 increasing doses of opioids to maintain a
2 defined effect, such as analgesia.

3 Physical dependence is the
4 occurrence of withdrawal symptoms after abrupt
5 discontinuation of a drug upon administration
6 of antagonist.

7 Physical dependence and tolerance
8 are not unusual during chronic opioid therapy.

9 Correct?

10 A. Correct.

11 Q. Significant tolerance should not
12 occur in most of the patients treated with the
13 lowest doses of OxyContin.

14 It should be expected, however,
15 that a fraction of cancer patients will develop
16 some degree of tolerance and require
17 progressively higher doses of OxyContin.

18 Regardless of whether this occurs
19 as a result of increased pain secondary to
20 disease progression or pharmacological
21 tolerance, dosage can usually be increased
22 safely by adjusting the patient's dose to
23 maintain an acceptable balance.

24 The dosage should be selected

1 according to the patient's individual analgesic
2 response and ability to tolerate side effects.

3 Correct?

4 A. You're asking me whether there's
5 substantial evidence or that's what the label
6 says?

7 Q. That's what the label says.

8 A. That's what the label says.

9 Q. Tolerance is the analgesic effect
10 of opioids usually paralleled by tolerance to
11 side effects, except for constipation.

12 So the label contained information
13 about both tolerance and physical dependence at
14 the time?

15 A. Made the -- it makes those
16 statements as you just read.

17 Q. Okay. And is there anything that
18 you say that the company knew that FDA did not
19 know about tolerance and physical dependence
20 that -- at that time?

21 A. Well, I don't want to -- knowledge,
22 I think, is a little -- I don't want to opine
23 on knowledge.

24 Q. Okay. So you're --

1 A. I mean, there's no substantial
2 evidence for some of that.

3 Q. You're not offering an opinion that
4 the company had information about tolerance and
5 physical dependence that the FDA did not have?

6 A. Not -- not specifically. I think
7 that the -- not that specific sentence, but if
8 you go down later in that paragraph, I would
9 have an opinion.

10 Q. Okay. What is it that you're
11 saying there isn't substantial evidence about?

12 A. Well, this using higher doses to
13 overcome tolerance is not -- there's not
14 substantial evidence that higher doses increase
15 therapeutic efficacy in the case of tolerance.
16 And, in fact, one -- I mean, many addiction
17 experts would say that you want to lower the
18 dose, and that's the appropriate treatment. So
19 there's not substantial evidence for that.

20 Moreover, what wasn't disclosed to
21 the agency was the game plan to significantly
22 increase the dose beyond what American medicine
23 was using.

24 Q. This is -- this is a discussion on

1 tolerance and physical dependence.

2 A. But it also -- it also -- in some
3 ways, the truck through that statement was on
4 higher doses, so it's relevant to the question
5 of whether you treat tolerance with higher
6 doses, because that -- that marketing plan that
7 you see throughout a number of years on higher
8 doses, I mean, got -- I mean, changed medicine.

9 Q. It says, Tolerance is the need for
10 increasing doses.

11 A. Right. But I'm talking about
12 several sentences down.

13 Q. Okay. So you're not saying that
14 the company knew something about risk of
15 tolerance or physical dependence at that point
16 in time that the FDA didn't know?

17 MR. RAFFERTY: Object to the form.

18 A. I think the company knew that it
19 had a marketing strategy to increase to higher
20 doses than it -- had been used, and I don't
21 think that was disclosed to the agency.

22 Q. So at this point in time, you have
23 approval of 10 milligrams, 20 milligrams, and
24 40 milligrams, correct?

1 A. Yes. You --

2 Q. Okay.

3 A. Yes. And you have -- you have, in
4 essence, in that 40 milligrams the equivalent
5 of 16 Percocets.

6 Q. Okay. And that was an approved
7 dosage?

8 A. Yes, exactly.

9 Q. And --

10 A. But --

11 Q. And it goes on to say, If OxyContin
12 is abruptly discontinued in a physically
13 dependent patient, an abstinence syndrome may
14 occur.

15 Correct?

16 A. Correct.

17 Q. So there was not -- the label at
18 that time also talked -- disclosed that
19 patients may experience an adverse effect if
20 the drug is abruptly withdrawn?

21 A. That's what -- that's what that
22 says.

23 Q. Okay. And then under the section,
24 Information For Patient Caregivers, if you go

1 down, it says, Patients should be advised that
2 OxyContin is a potential drug of abuse. They
3 should protect it from theft, and it should
4 never be given to anyone other than the
5 individual for whom it was prescribed.

6 Correct?

7 A. Correct.

8 Q. Okay. So with this first label,
9 there is discussion about tolerance,
10 dependence, withdrawal, habit formation, and
11 OxyContin being a drug of abuse, correct?

12 A. Shouldn't have changed American
13 medicine, right?

14 Q. Okay.

15 A. Or prescribing habits.

16 Q. This was -- I'm just -- can we
17 agree that that's all in the label? Correct?

18 A. What's in the label, in and of
19 itself, we can get -- except for that higher
20 doses, should not have changed American
21 medicine.

22 Q. And there's also a discussion of,
23 drug abuse and dependence (addiction).

24 Correct?

1 A. Correct.

2 Q. So I don't -- the record will
3 reflect what it will reflect, but I think that
4 when we were talking, you said you weren't sure
5 that addiction was referenced in the original
6 label. This takes away the uncertainty on
7 that?

8 MR. RAFFERTY: Object to the form.

9 A. No. I certainly recognize -- if I
10 said that, I misspoke, because I certainly
11 recognize that addiction and, certainly, the
12 terms "abuse liability" that follow in several
13 sentences -- I know these sentences by heart.

14 Q. Okay. And it says, under Drug
15 Addiction, Drug dependence, psychological
16 dependence is characterized by a preoccupation
17 with the procurement/hoarding of abusive drugs
18 for non-medicinal purposes. Drug dependence is
19 treatable utilizing a multidisciplinary
20 approach, but relapse is common.

21 Did I read that correctly?

22 A. Correct.

23 Q. Okay. And then there's language we
24 all know: Iatrogenic addiction to opioids

1 legitimately used in the management of pain is
2 very rare.

3 Drug-seeking behavior is very
4 common to addicts.

5 Tolerance and physical dependence
6 in pain patients are not signs of psychological
7 dependence. Preoccupation with achieving
8 adequate pain control -- pain relief can be
9 appropriate behavior in a patient with poor
10 pain control.

11 Did I read that correctly?

12 A. Correct.

13 Q. So in the original '96 label, you
14 have language about addiction, dependence,
15 drug-seeking behavior. And although not called
16 pseudoaddiction, there is a recognition of the
17 potential for drug-seeking behavior in
18 inadequately treated patients, correct?

19 A. There is that exact sentence as you
20 read it.

21 Q. Okay. And then the label was
22 modified in 2001, correct?

23 A. Correct.

24 Q. And we've talked about the

1 interactions between the agency and the company
2 with regard to that label change, correct?

3 A. Correct.

4 Q. And in fact, what resulted was the
5 product having a boxed warning?

6 A. Among other things.

7 Q. And I'm going to ask you to look
8 first at the letter that accompanied --

9 MS. FREIWALD: What am I doing
10 wrong here with the Elmo that I'm --
11 that the corner is kind of --

12 MR. RAFFERTY: I think you just
13 need to zoom out.

14 VIDEO OPERATOR: No. That's up --
15 that's up here.

16 MR. RAFFERTY: Oh. Oh, I've got
17 you.

18 MS. FREIWALD: Oh. I'm good now?
19 Okay.

20 MR. RAFFERTY: If you want, I think
21 you can zoom out --

22 MS. FREIWALD: Yeah.

23 MR. RAFFERTY: -- and maybe --

24 MS. FREIWALD: No, I was -- there

1 was just --

2 MR. RAFFERTY: Okay.

3 MS. FREIWALD: There was stuff
4 hanging over the edge there.

5 MR. RAFFERTY: Oh.

6 MS. FREIWALD: That's what I was
7 addressing.

8 MR. RAFFERTY: Sorry. I
9 misunderstood.

10 MS. FREIWALD: So I want everybody
11 to be able to read it --

12 MR. RAFFERTY: Okay.

13 MS. FREIWALD: -- so I'll try to
14 keep it readable for folks. You can
15 tell me if it's not.

16 Q. So when there -- would you agree
17 with me, sir, that when there are significant
18 label changes, the agency can require that the
19 company send a "Dear Healthcare Provider"
20 letter to give doctors real notice of that
21 label change?

22 A. Let's edit the word "require."
23 Urge strongly.

24 Q. Okay. So they can urge strongly.

1 And companies tend to do what the FDA urges
2 them strongly to do, and in this case --

3 A. You're -- I mean --

4 Q. In this case -- I'm not going to
5 quibble with you whether it was required or
6 whether it was simply recommended. The record
7 will be what it will be on that.

8 But I think we can agree that
9 Purdue did send out a "Dear Healthcare
10 Provider" letter accompanying the 2001 label,
11 correct?

12 A. Correct.

13 MR. RAFFERTY: Object to the
14 preamble and the editorial comments at
15 the beginning.

16 Q. And, in fact, the way these letters
17 come is that there's this label on the very
18 front so that when the doctor gets something in
19 the mail, it says, "Important drug warning,"
20 and they can see right away that that's
21 important information about a product from
22 Purdue, correct?

23 A. Can be, yes.

24 Q. And the "Dear Healthcare Provider"

1 letter that accompanied the label in 2001 said,
2 Reports of illegal use, misuse, and diversion
3 of OxyContin tablets from various parts of the
4 country have prompted Purdue Pharma to revise
5 sections of the prescribing information,
6 specifically warnings, including a new box
7 warning, which call attention to the potential
8 for misuse, abuse, and diversion, and
9 indication, which reinforces the appropriate
10 patient population for whom this product is
11 intended.

12 Did I read that correctly?

13 A. Correctly.

14 Q. Okay. And then it goes on to say,
15 OxyContin is a Schedule II opioid agonist and a
16 Schedule II controlled substance.

17 Correct?

18 A. Correct.

19 Q. And by the way, in order to
20 prescribe OxyContin or any Schedule II opioid,
21 a doctor needs a special DEA registration,
22 correct?

23 A. You certainly need DEA
24 registration, and depending on the state, there

1 are certain other requirements that States may
2 impose.

3 Q. Okay. So if a doctor is
4 prescribing prescription opioids, he or she is
5 taking on an additional level of responsibility
6 and knows that?

7 MR. RAFFERTY: Object to the form.

8 A. That was what was changed.

9 Q. So then it goes on to show the box
10 warning, OxyContin is an opioid agonist and a
11 Schedule II controlled substance with an abuse
12 liability similar to morphine.

13 Did I read that correctly?

14 A. That's what that says.

15 Q. So when you say that the product --
16 that Purdue did not advise of an abuse
17 liability similar to morphine, sir, it said it
18 right in the label, correct?

19 MR. RAFFERTY: Object to the form.

20 A. Oh, I -- go look at your
21 promotional materials. Your -- all marketing
22 campaigns were to distinguish and to remove the
23 stigma associated with morphine. That was a
24 very explicit strategy that was carried out.

1 The issue is not the label; the issue is the
2 promotion.

3 Q. Is there any example that you found
4 from -- any time from 2007 on where the company
5 says that the product has a different abuse
6 potential than morphine?

7 A. I'd have to check. There are call
8 notes that -- in my report and in the schedule,
9 and I'd have to go check those call notes.

10 Q. I think you told me on the break
11 that there were two call notes after 2003.

12 A. No. There are actually more in the
13 schedule, and I'd have to review that.

14 Q. In the report?

15 A. There are -- there are a handful.
16 I just tried to limit it. But the schedule is
17 the report, too.

18 Q. Of the ones you actually discuss in
19 your report, they're all earlier, except for
20 two, and we'll talk about those later.

21 A. Three.

22 MR. RAFFERTY: Object --

23 A. I think there's three.

24 Q. I think it's two.

1 A. Well, okay.

2 Q. But anyway --

3 MR. RAFFERTY: Objection.

4 Q. We'll look at the page.

5 A. Fine.

6 MR. RAFFERTY: The report says what
7 it says.

8 Q. So you haven't discussed any
9 examples from mid-2000s on of --

10 A. You --

11 MR. RAFFERTY: Wait. Let her
12 finish the question.

13 Q. -- of any marketing by Purdue which
14 is saying that OxyContin has a different abuse
15 liability than morphine?

16 A. The stage was set. Your -- I
17 mean --

18 Q. Just answer my question.

19 A. That's correct. The stage was set.

20 Q. I'm going to --

21 A. The change in American medicine
22 happened by 2007 and then was continued by
23 other defendants.

24 Q. I'm going to just, because we have

1 very limited time, take it as a given that your
2 view of this litigation is that whatever
3 happened from 2003 earlier, doctors couldn't
4 learn anything.

5 Is that your testimony?

6 MR. RAFFERTY: Object to the form.

7 Misstates his testimony.

8 Q. Is that your testimony, that
9 doctors were unable to learn from their patient
10 experience, from conferences, from changes in
11 the literature, from changes in the label, from
12 talking to their colleagues, from public
13 AdComs, from citizens' petitions?

14 None of that was capable over
15 15-plus years of educating doctors?

16 MR. RAFFERTY: Object to the form.

17 A. No, that's incorrect. That was,
18 but there was a constant pushback.

19 And if you look at the -- the
20 script or the playbook that your company, along
21 with Abbott, had developed in marketing
22 OxyContin, that was continued along the same
23 lines: lower abuse, less abuse liability --
24 maybe sometimes more subtly, less peaks, less

1 valleys.

2 But that, there was a constant
3 selling of opioid -- prescription opioids under
4 those theories --

5 Q. So --

6 A. -- and in marketing plans.

7 Q. So I have not seen any consistent
8 references in your Purdue report to anything
9 post- early to mid-2000s.

10 MR. RAFFERTY: Object to the form.

11 A. No, that's incorrect. Your company
12 continued to detail this and promote this
13 through sales representatives after this
14 country is in florid epidemic.

15 Q. I didn't ask you whether they
16 continued to have a sales force and detail
17 that.

18 That's lawful, by the way, right?
19 It's lawful for all of these companies to have
20 had sales forces --

21 MR. RAFFERTY: Object to the form.

22 Q. -- for their products?

23 A. Well, you just read me what you --

24 Q. Just answer my question, because --

1 I'm going to try and break it down, because
2 we're not communicating here.

3 A. No, but we're --

4 MR. RAFFERTY: Enough with the
5 commentary and the edits -- the
6 editorials.

7 Q. We're --

8 A. So may -- may I ask you a question?
9 Yes, it was lawful, but after what you just
10 read me -- why in the world would you go out
11 and promote this drug the way you did, in light
12 of what you just read me?

13 Q. Sir, we're going to break --

14 A. It makes no sense.

15 Q. We're going to break this down into
16 pieces, and I just want to know -- I don't want
17 to argue with you today. I just want to know
18 what you're relying on and what --

19 So first of all, we can agree that
20 Schedule II opioids can be promoted? There's
21 nothing that says --

22 A. Why in the --

23 Q. I -- just answer, sir.

24 A. Why in the world --

1 Q. Answer --

2 A. -- would you go promote a
3 Schedule II opioid?

4 Q. Answer my --

5 A. It makes no sense.

6 Q. Answer -- answer my question.

7 A. Yes.

8 Q. It is lawful to promote Schedule II
9 opioids, correct?

10 A. That's correct, but it makes no --

11 Q. Okay. So that's --

12 A. -- but it make no sense.

13 Q. I'm not asking you --

14 A. Let me please finish.

15 Q. -- that opinion.

16 A. I think I've made -- I think you
17 understand my point. It makes no sense in the
18 midst of an epidemic to go promote Schedule II
19 opioids. I've never understood that.

20 Q. I understand that may be your
21 personal opinion, but it is entirely lawful --

22 A. It's the opinion of your company --

23 Q. It is --

24 A. -- as of -- as of now.

1 Q. It is -- sir, it's entirely lawful
2 to promote Schedule II opioids, correct?

3 A. Well, you'll -- I mean, again, I
4 don't want --

5 Q. It's a yes or no.

6 MR. RAFFERTY: First of all,
7 objection.

8 Q. It's lawful?

9 MR. RAFFERTY: It's been asked and
10 answered.

11 A. Well, again, I don't want to give
12 any legal opinions.

13 Q. The regulations that you are
14 familiar with as former Commissioner of the FDA
15 make clear that -- that it's -- you can promote
16 Schedule II opioids?

17 A. We wouldn't be sitting here if
18 there wasn't a question --

19 Q. Sir, it's a yes or no. Do the
20 regulations --

21 MR. RAFFERTY: Don't interrupt the
22 witness.

23 A. So it depends on what law you're
24 talking about. Did you create a public

1 nuisance? Is that lawful?

2 Q. Sir, the regulations -- you can
3 either tell me yes, no, or you don't know.

4 Do the regulations allow for the
5 marketing of Schedule II opioids?

6 A. Which regulations are you referring
7 to?

8 Q. FDA regulations.

9 A. FDA regulations do not prohibit the
10 promotion of Schedule II opioids, and that's
11 why -- but FDA is not the only system of
12 consumer protection.

13 Q. And the -- in fact, they would have
14 allowed direct-to-consumer TV ads, which my
15 client did not use, correct?

16 A. Your -- the other companies wanted
17 to. There were --

18 Q. Sir --

19 A. Okay. Hold on a second.

20 Q. -- it's just a simple question.

21 I'm not asking you what you think should have
22 happened in a different world.

23 I'm just asking, there was no
24 television DTC promotion of OxyContin, correct?

1 A. There was indirect DTC --

2 Q. I asked you --

3 A. -- not on television, but you used
4 certain pain groups to do, in essence, DTC.

5 Q. That is not DTC, sir.

6 A. It's direct to consumer.

7 Q. Okay.

8 A. You did it under disguise.

9 Q. All right.

10 A. Of course, it's direct to consumer.

11 Q. So is it your testimony that the
12 label in 2001 reasonably described the risk of
13 abuse, addiction, misuse? Yes?

14 A. Not if the intent -- the intended
15 use was as your company had for the product.
16 The label was not adequate to protect against
17 your company's conduct.

18 Q. The label as written describes the
19 fact of misuse, abuse, and diversion of
20 OxyContin, correct?

21 MR. RAFFERTY: Object to the form.

22 A. I -- I agree with you --

23 Q. Okay.

24 A. -- what the label says, but just so

1 you -- just so --

2 Q. Sir --

3 A. -- so we can be -- maybe make this
4 very short, this --

5 MS. LEVY: Object to the
6 commentary.

7 Q. No. I want to -- I want to ask you
8 questions, and I want to get answers to my
9 questions.

10 A. Okay.

11 MR. RAFFERTY: Well, you -- just
12 because you're not getting the answer
13 you want doesn't mean he's not answering
14 your question.

15 Q. And I don't want to hear the speech
16 about the theory of the case or you stepping in
17 to be a lawyer --

18 MR. RAFFERTY: Objection.

19 Q. -- opining about the other theories
20 of the case. I just --

21 You'll have lots of chance with
22 your own counsel to say what you want to say to
23 a jury one day, but I just want to understand
24 where we agree or where we disagree. Okay?

1 MR. RAFFERTY: Objection to all the
2 commentary.

3 Q. So the label in 2001, you will
4 agree with me, discusses reports of misuse,
5 abuse, and diversion of OxyContin?

6 A. The label says what it says.

7 Q. Okay. And it discusses the
8 addiction potential of OxyContin, correct?

9 A. The label says what it says.

10 Q. And it says that there's no
11 difference between OxyContin, in terms of abuse
12 potential, and morphine, correct?

13 A. That's -- that's not the -- well,
14 that's -- you're reading from the letter.

15 Q. Well, this is just an excerpt of
16 the box warning.

17 A. I understand, but you're reading
18 from the letter, just so the record --

19 Q. Well, I can show you the version of
20 it in the label, if you would -- if you would
21 prefer. I'd be happy to do that.

22 A. I'm agreeing with you, the label
23 says what it says.

24 Q. Okay. And the label talks about

1 not crushing or chewing, correct?

2 A. Correct.

3 Q. Okay. Now -- and I assume that you
4 will also agree with me that the label talks
5 about tolerance and dependence?

6 A. It says exactly what it says.

7 Q. And it talks about the potential
8 for drug-seeking behavior, which is -- in
9 patients who are not adequately treated, which
10 may be signs of addiction or may be inadequate
11 treatment, correct?

12 A. We discussed that earlier.

13 Q. Okay. So -- and you're not
14 disputing that the label in 2001 was sent
15 directly to doctors with a cover warning
16 indication, correct?

17 A. It was sent out. I'm not going to
18 represent who it was sent out to.

19 Q. Okay.

20 A. The evidence can show that.

21 Q. And you're not going to dispute
22 with me, if I show you the label in 2014, that
23 there continued to be -- that the FDA actually
24 approved higher doses?

1 MR. RAFFERTY: I don't -- I don't
2 have that.

3 MS. FREIWALD: I thought I gave
4 you -- Exhibit 5.

5 MR. RAFFERTY: Oh, sorry.

6 Q. That the FDA went on and --

7 A. What label are you showing me?

8 Q. In 2014. It actually happened
9 before 2014, but --

10 A. That's correct.

11 Q. -- but that higher doses were
12 approved?

13 MR. RAFFERTY: Exhibit 5, right
14 there in front of you.

15 A. Well, I mean, and there was also
16 taking a higher dose off the market.

17 Q. That's the 160.

18 A. Yes. I'm just --

19 Q. Okay. And that was something the
20 company did; they withdrew the 160-milligram
21 product, correct?

22 A. I believe with FDA.

23 Q. Okay. So that was -- that was an
24 example of, post-approval, the ability to

1 withdraw a product or a dose of a product?

2 MR. RAFFERTY: Object to the form.

3 A. A company can do anything it wants
4 after -- the company could stop selling it.

5 Q. And by the way, will you agree with
6 me as well that there's language in the label
7 and in the prior labels about significant
8 respiratory depression risk?

9 A. There is.

10 Q. Okay. And that goes back to 1996?

11 A. Correct.

12 Q. And so you're not disputing that
13 the label had the language about that risk
14 information?

15 A. I'm not disputing any -- I'm just
16 disputing how it ended up being promoted the
17 way it did with this label the way it was.

18 Q. And you're not -- I think you had
19 testimony that there was -- that the risk of
20 respiratory depression was downplayed.

21 In fact, the box warning talked
22 about, Serious life-threatening or fatal
23 respiratory depression may occur. Monitor
24 closely, especially upon initiation or

1 following a dose increase.

2 Correct?

3 A. The promotional campaign to go
4 higher doses, in my opinion, downplayed those
5 risks of overdose. It was the push toward
6 higher doses that downplayed that, not what was
7 said in the label.

8 Q. And are you aware, sir -- I don't
9 think it's cited in your report -- that
10 Senator Blumenthal, who was not a senator at
11 that point, wrote to the FDA in 2008 with
12 regard to one of the issues that you have in
13 your report, which is the q12 versus q8 dosing?

14 A. Correct.

15 Q. And, in fact, was --

16 MS. FREIWALD: I'm going to mark
17 this as Exhibit 8.

18 (Exhibit Kessler-8 marked for
19 identification and attached to the
20 transcript.)

21 BY MS. FREIWALD:

22 Q. And this is the FDA's response to
23 that letter from Richard Blumenthal, who was
24 then the Attorney General in the State of

1 Connecticut, in 2008, correct?

2 And you don't talk about this in
3 your report, do you?

4 A. I do not talk about this petition
5 because I -- I'm not sure -- I have to
6 review -- I think the senator gets a little
7 wrong the pharmacokinetics, as I remember, when
8 I first read this, and I -- so I found this a
9 little confusing, what his citizens' petition
10 was.

11 Q. Okay. And the issue at this time
12 had to do with -- if you look at the
13 discussion, You assert that the incidence of
14 prescribing OxyContin at dosing intervals more
15 frequent than the recommended every 12 hours
16 has risen, at least in part, because of
17 fundamental misunderstanding by healthcare
18 providers of OxyContin's unique drug delivery
19 system; certain patients receiving OxyContin at
20 intervals more frequently -- more frequent than
21 q12 are more at risk of developing side effects
22 and potentially serious adverse reactions
23 because of the pharmacologic action of the
24 drug; and increasing the number of doses beyond

1 the recommended two-per-day increase the
2 potential for diversion of the drug for illicit
3 use and abuse, and -- sorry -- and you request
4 that FDA require Purdue to strengthen the black
5 box warning statement, supplement the
6 information in warning in the label, and issue
7 a "Dear Healthcare Provider" letter.

8 In the alternative, you request
9 that FDA disseminate these warnings through a
10 safety alert/public health advisory.

11 Correct?

12 A. If you can get -- if you can kindly
13 just give me what Blumenthal was asking the
14 agency specifically to put on the label?
15 Because I just don't have that in front of me.

16 Q. You didn't discuss this letter that
17 was discussing risks of dosing other than q12,
18 correct, in your report?

19 A. I don't know whether this is --
20 I've read this. I don't know if it's cited on
21 my reliance material because this letter --
22 this letter in Blumenthal's -- I mean, don't --
23 actually miss the pharmacokinetic issue and the
24 push toward higher doses.

1 Q. You have a section in your report
2 where you're talking about q12 dosing.

3 And, in fact, Mr. Blumenthal, as AG
4 of Connecticut, had written to the FDA, and
5 there was a full discussion of q8 versus q12
6 dosing, and the FDA determined not to do
7 anything.

8 A. You're missing the point,
9 Counselor. This has nothing -- this is -- this
10 is different than the issue I raised in my
11 report.

12 The fact -- what I raised in my
13 report was the fact that because of the -- as
14 you can see in the clinical trials, the
15 significant use of rescue doses, that did
16 not -- those rescue doses indicated that -- and
17 the pharmacokinetics, if you look at it
18 carefully, indicate that it doesn't work -- the
19 medicine doesn't work for q12 hours and that --

20 The solution that your company came
21 up and didn't tell FDA about and is not
22 reflected in this petition or in FDA's
23 response -- that your marketing plan was,
24 rather than go to q8, right, your company said,

1 push the dose higher. And that -- that exposed
2 people to higher risks of higher doses. That's
3 what's missing here.

4 Q. Sir --

5 MS. LEVY: Objection, long.

6 MR. RAFFERTY: Good objection.

7 Q. Sir, you --

8 MR. RAFFERTY: I mean that
9 sarcastically.

10 Q. Your opinions about q12 dosing are
11 exactly the opposite of what the concerns were
12 at the time, correct?

13 A. Because they -- because they didn't
14 have access to what your marketing plan was and
15 what was going on.

16 Q. And the FDA knew about the use of
17 rescue dosing in clinical trials, correct?

18 A. They knew that. They didn't know
19 the push toward higher doses.

20 Q. And they, in fact, had drugs that
21 were approved, including by you, for rescue
22 dosing, correct?

23 A. There were drugs approved for
24 rescue dosing, but --

1 Q. And rescue dosing is --

2 MR. WEINBERGER: Can you let him
3 finish his answer?

4 MS. FREIWALD: That was my only
5 question.

6 MR. WEINBERGER: But he didn't
7 finish his answer.

8 Q. There were drugs approved for --

9 MR. WEINBERGER: He didn't finish
10 his answer.

11 MS. FREIWALD: I think we have one
12 party --

13 MS. LEVY: Well, it's totally
14 inappropriate --

15 MS. FREIWALD: That's totally --

16 MR. WEINBERGER: But you can
17 question -- but you can -- you can state
18 your objection, even though you're not
19 the questioner?

20 MS. FREIWALD: All right. We have
21 limited time here.

22 (Simultaneous speaking.)

23 MR. RAFFERTY: We have limited
24 time, and there's only one person for

1 your side.

2 MS. LEVY: I'm not doing it in a
3 yelling and unprofessional manner.

4 MS. FREIWALD: Yeah.

5 MR. WEINBERGER: You know, don't
6 talk to me about being unprofessional.
7 You did exactly what I just did.

8 MS. FREIWALD: This is either going
9 to come from your time, or it's going to
10 stop.

11 Q. The -- the FDA, whether you -- the
12 FDA certainly had the issue of dosing put in
13 front of it, even if you say in a different
14 context than what your issue was, and it did
15 not believe that there was either a need for
16 more data on q8 or q12 dosing or a problem with
17 q12 dosing?

18 MR. RAFFERTY: Object to the form.

19 A. Your company -- your client --
20 sorry -- recognized the problem and implemented
21 a plan to increase -- to put patients on higher
22 dosing. That was never disclosed to the FDA.
23 That's what put patients at risk.

24 Q. Sir, you say "higher dosing" --

1 MR. RAFFERTY: Objection. Let him
2 finish his answer. He's addressing the
3 exact question that you asked.

4 Q. You say "higher" --

5 MR. RAFFERTY: Finish your answer.

6 A. If something is not working at q12
7 and your client's sales force was getting
8 repeat complaints, right, about the drug not
9 working at q12, because they were afraid that
10 your competitors, right, would increase their
11 market share because their drugs were q4 to 6,
12 right, and you could no longer have the special
13 characteristic at q12, you -- you strongly --
14 the marketing plan pushed and instructed the
15 sales force.

16 And you see this throughout --

17 Q. Sir --

18 A. Can I just finish?

19 You see this throughout the call
20 notes, this push towards, Do not allow doctors
21 to go to q8. Have them go to higher doses.

22 And the end result of that is the
23 consumption -- one, it was higher doses, higher
24 bonuses. But it was also higher doses, more

1 drug in distribution; and it was also higher
2 doses that increased the risk of overdose and
3 death.

4 Q. Sir --

5 A. And that was never disclosed or in
6 that label; if it doesn't work at q12, do you
7 go to higher doses?

8 Q. Sir -- sir, you have not cited a
9 single document that indicates that there was
10 any push to doses that were above approved
11 doses.

12 A. You have --

13 Q. There's a -- there's a dosage
14 continuum, right?

15 MR. RAFFERTY: There's a question
16 pending.

17 Q. There's a dosage continuum, right,
18 10, 20, 40, 60? You don't -- none of --

19 Just answer my question, then we'll
20 move on.

21 MR. RAFFERTY: Well, get to the
22 question.

23 Q. You're not citing to anything that
24 shows a push to doses that were other than

1 approved or that the FDA ever took a position
2 that you couldn't use higher doses?

3 A. The -- there was -- you're talking
4 about product strength. There was a push
5 toward higher and higher doses, right, even
6 though --

7 Q. I just said --

8 A. And there was certainly multiple
9 tablets that were consumed, okay. There were
10 patients on extraordinary amounts of MMEs. And
11 the campaign was higher doses to cover the fact
12 that it didn't work at q12.

13 Q. Do you -- do you know what
14 percentage of patients --

15 MR. RAFFERTY: Excuse me. Once
16 again, let the record reflect that she
17 is interrupting the witness constantly.

18 MS. FREIWALD: Because he's not
19 answering my --

20 MR. RAFFERTY: You asked him what
21 he was citing to in regards to this, and
22 he was going through, and in a very
23 concise paragraph, almost shorter than
24 the one that you -- it took you to ask

1 the question, exactly what he was citing
2 to.

3 MS. FREIWALD: No, he did not.

4 MR. RAFFERTY: That's exactly what
5 he did.

6 Q. Is there -- do you reference, first
7 of all, any data from Ohio on the percentage of
8 patients who were prescribed at any particular
9 dose?

10 A. I don't believe I do. I'd have to
11 check.

12 Q. So when you say "push to higher
13 doses," you don't know whether you're talking
14 about 10 to 20, 20 to 40?

15 A. Oh, I -- I certainly -- these were
16 talking about -- this is one -- wasn't 10 to
17 20. These -- when you look at these call notes
18 and you see these --

19 Q. The call notes are all, we've
20 agreed --

21 MR. RAFFERTY: Once again --

22 Q. -- early call notes.

23 MR. RAFFERTY: Once again, stop
24 interrupting the witness. You ask him a

1 question, he's answering it, and then
2 you interrupt him to ask him a different
3 question.

4 Q. I want to --

5 A. Can I have a second?

6 Q. Yeah.

7 A. Thanks. Make sure I -- see if I
8 can get you an answer.

9 Q. The call notes are going to be for
10 pre-2007 with, I think, two exceptions that are
11 not related to this issue.

12 MR. RAFFERTY: Objection, misstates
13 the prior testimony.

14 A. So here, for example -- so take
15 Cuyahoga County, call note written. It says,
16 Saw him at Suburban. He is still mentioning q8
17 dosing, so it's important to get him very
18 specific with patient types, what they were on,
19 what dose. He says is not lasting the full q12
20 hours.

21 Q. Sir, the product was approved as a
22 q12 product, correct? It would have been
23 improper to promote it as a q8 product?

24 A. But when -- but when you find

1 out --

2 Q. Just answer the question.

3 A. It would have been proper to inform
4 the FDA that the product wasn't working and it
5 wasn't designed to work q12.

6 And you should have informed -- and
7 you certainly should not go to say the
8 solution, when the product doesn't work --

9 Q. Sir --

10 A. -- at q12, to increase higher
11 doses.

12 Q. The fact that a --

13 A. That was improper. That was
14 information -- that is safety information that
15 your company had an obligation to change.

16 Q. Can we -- can we stop for a second?

17 Would you agree with me that not
18 every patient responds properly at the first
19 dose given? You start at a low dose, and you
20 see if it works as you go up, correct?

21 A. No. Your company had --

22 Q. Sir, just answer my question.

23 That's part of what you're supposed
24 to do, start at the lowest possible dose, and

1 for some people it will work, and for some
2 people it won't, and you need to go -- you may
3 need to go up, correct?

4 A. Perhaps --

5 Q. Okay.

6 A. Let me finish the sentence.

7 Perhaps if you're talking from 5 to
8 10 to 15 to 20. But when you're pushing
9 patients to 40, to 80, to multiple tablets,
10 to --

11 Q. Sir --

12 A. -- sometimes in excess of that --

13 Q. -- I'm --

14 A. That is what was going on.

15 Q. I just want to ask my questions.

16 You can answer. And I really -- I'm going to
17 strike the colloquy, because we have a limited
18 amount of time here.

19 MR. RAFFERTY: Oh, you've already
20 ruled on the strike?

21 Q. The -- the way it's appropriate, to
22 start a patient at the lowest possible dose,
23 and if it doesn't work, which could mean not
24 providing pain relief for the full 12 hours,

1 titrating to a higher dose to see if it works
2 is an appropriate approach?

3 A. But when you find -- no. When you
4 find that your tablets are not working because
5 of --

6 Q. Just --

7 A. I can't answer the question.

8 Q. I want to know if you -- if that is
9 an -- if that is actually a recommended
10 approach, whether -- start low, and if the
11 patient isn't getting relief for the full time
12 period, one thing to do is to try to titrate
13 up?

14 A. No. I think that's one of the
15 fallacies, right, that was created in opioid
16 pharmacology. This notion that you just
17 titrate up, I mean, I think doctors are
18 recognizing -- you talk about learnings. I
19 think your company had an equal obligation to
20 talk about titrating down.

21 Q. Okay. And there was that -- sir,
22 the drug is a q12 drug, it's labeled as a q12
23 drug, and if a patient is not getting relief
24 for the full 12 hours, one appropriate option

1 is to say, titrate up and see if that works.
2 If it doesn't work, then the doctor can decide
3 the drug isn't working.

4 A. No. When you learn that a drug is
5 not working q12 hours and that -- you have
6 to -- when it's not working q12 hours, you have
7 to inform the agency that, my product -- I have
8 safety information that this product is not
9 lasting q12 hours.

10 And the solution is not to
11 recommend just going higher and higher to try
12 to cover this tail -- this period of time that
13 you're never going to be able to work. That's
14 how you get people into serious trouble.

15 Q. And do you have -- do you have any
16 controlled trial that supports your view that
17 rescue dosing or titrating up led to an
18 increase in adverse events?

19 A. You certainly have. I'd be happy
20 to go through the entire literature on the
21 effects of higher dosage and overdose --

22 Q. Well, I haven't seen that in --

23 MR. RAFFERTY: Let him finish. You
24 asked if he had any clinical trials;

1 he's answering.

2 Q. In the second --

3 MR. RAFFERTY: No.

4 Finish your answer, Doctor. Finish
5 it.

6 A. There are a number of papers in a
7 footnote by Musto and others that talk about
8 higher doses. Number of pages in the
9 bibliography, there is certainly footnotes on
10 higher doses.

11 The evidence, I think, is
12 overwhelming that -- and everybody agrees that
13 there's certainly an increased risk at higher
14 doses. It was not proper conduct to increase
15 those doses.

16 Q. If the company had told doctors,
17 Don't use it q12, use it q8, you would be
18 faulting them for that, correct?

19 A. No. I would have --

20 MR. RAFFERTY: Object to the form.

21 A. -- said that if you learn that
22 your -- your pill -- as your competitors --
23 some of your competitors figured out, right,
24 not true q12 dosing -- just look at the

1 pharmacokinetics, look at the clinical trial
2 data -- you have an obligation to go in to the
3 agency, not to expose patients to serious risks
4 of opioids.

5 Q. There was --

6 A. This was not something that should
7 have just -- higher doses. This was about
8 bonuses. This was about more tablets being
9 sold. You lost sight --

10 Q. Sitting here today --

11 A. You lost sight of --

12 Q. Sir.

13 A. -- the fact that these are very
14 dangerous products.

15 Q. Sir, sitting here today, have you
16 done an analysis of what percentage of patients
17 in Ohio, in the counties at issue, got any
18 particular dose of OxyContin at any particular
19 point in time?

20 A. What I -- what I tell can you --

21 Q. It's a simple question. Have you
22 done the analysis?

23 A. Yeah, so -- so the -- what I have
24 done, the analysis, is that -- as you know,

1 your company's marketing --

2 Let me finish my answer, please.

3 Your company's marketing plans were
4 national in scope. So I do have data on 40s,
5 60s, 80s and what -- they were national -- and
6 I've looked at the data, and I see no reason to
7 think -- there's no reason to suspect, because
8 these were -- this was a -- these were national
9 programs --

10 Q. Do you know --

11 A. -- that Ohio is anything different.

12 Q. Nationally, do you know what
13 percentage of patients were taking 40s or less?

14 A. I can get you that data. I have it
15 here, but I --

16 Q. You didn't put it in your report?

17 MR. RAFFERTY: Object to the form.

18 A. There's a lot of -- ma'am, at 350
19 pages and a thousand footnotes --

20 Q. You --

21 A. -- I put what I could. But you're
22 asking me questions that --

23 Q. You're accusing my client of
24 pushing doses --

1 MR. RAFFERTY: Object to the form.

2 Q. -- and you didn't put in your
3 report what percentage of patients were
4 actually taking above 20 or 40 milligrams?

5 MR. RAFFERTY: Object to the form.

6 A. I put the evidence of your company
7 pushing higher doses.

8 Q. But you don't actually -- you
9 didn't put any evidence of result, of what
10 percentage of patients were actually taking a
11 particular dose, including for the last ten
12 years. That's not in your report?

13 A. I can go back and look. My report
14 does -- and others will testify on the
15 consequences of the epidemic and what that led
16 to.

17 Q. And there were discussions with FDA
18 about break-through pain, correct?

19 A. There were some discussions
20 about -- justifying the clinical trial data --

21 Q. Right.

22 A. -- because you couldn't -- the
23 clinical trials didn't support q12. So it was
24 a cover for why the --

1 Q. Sir --

2 A. It was a cover for why the -- how
3 to get the drug approved.

4 Q. You told me you weren't going to
5 talk about anybody's intent, that you weren't a
6 mind reader and know what anybody intended.

7 A. I'm not.

8 Q. So there was information provided
9 about rescue dosing; there was discussion about
10 rescue dosing, correct?

11 A. Yes.

12 Q. There was discussion about
13 percentages of patients who got q12 relief and
14 percentages who did not, correct?

15 A. Correct.

16 Q. There was -- there was adverse
17 event reporting on patients who complained or
18 reported not getting relief, or doctors who
19 did, on q8 -- on q12 dosing?

20 A. I don't think that was fully
21 reflected in the adverse event report.

22 Q. Did you look?

23 A. Yes. I looked at the sales call
24 notes and --

1 Q. I didn't say sales call notes; I
2 said adverse event reports.

3 A. No, I understand. But the sales
4 call notes tell you what the doctors were
5 reporting, and you can trace those through to
6 the adverse event.

7 Q. They're two entirely different
8 things.

9 MR. RAFFERTY: Object to the form.

10 Q. You don't know what went in as an
11 adverse event.

12 A. No. No, but -- that's my point
13 exactly. You do, ma'am. That's why the sales
14 call note is, in essence, a complaint. If a
15 doctor reports that's not working at q8, that
16 gives you that information that should trigger
17 a complaint that should trigger an adverse
18 event.

19 Q. Do you know what --

20 MR. RAFFERTY: Stop interrupting.

21 Q. Do you know what -- what got
22 triggered in terms of adverse event reporting
23 in the last ten years by the sales force when a
24 problem about q12 dosing was reported?

1 A. I've not studied specifically that
2 question for the last ten years.

3 Q. Okay. And so for the last ten
4 years, you haven't looked at what the FDA
5 understood about the post-marketing experience
6 of patients with q12 dosing as reflected in
7 adverse event reporting, correct?

8 A. Incorrect.

9 Q. You just said you hadn't studied
10 it.

11 A. No, I -- but I certainly know
12 what -- you know, I'm sorry. You asked me what
13 the company's adverse event policy was. That
14 was the question that I said I had not studied
15 over the last ten years.

16 I certainly know, because I've had
17 discussions.

18 Q. I didn't ask policies.

19 MR. RAFFERTY: Please stop
20 interrupting him.

21 MS. FREIWALD: Well, he's --

22 MR. RAFFERTY: No. You -- you
23 asked, and he said --

24 MS. FREIWALD: -- answering the

1 question based on what I said. I didn't
2 say that.

3 MR. RAFFERTY: You said, You just
4 said you hadn't studied it, and he's
5 explaining how he answered the question.

6 A. I certainly understand FDA's --
7 I've talked to the agency about q12 hour --
8 those questions have come up and --

9 Q. When did you do that?

10 A. They were in general conversations
11 that I've had.

12 Q. With whom?

13 A. I'd have to go back and try to sort
14 out who that was with.

15 Q. Okay. In 2013, there was a
16 citizens' petition filed by PROP, correct?

17 A. Correct.

18 Q. And that citizens' petition
19 asked for --

20 MS. FREIWALD: Do we have copies of
21 it?

22 Because we're slow in time -- short
23 on time here, I'm going to just mark
24 this as Exhibit 9.

1 (Exhibit Kessler-9 marked for
2 identification and attached to the
3 transcript.)

4 BY MS. FREIWALD:

5 A. I have PROP in front of me.

6 Q. Okay. And I'll give out other
7 copies later. I apologize. So -- but I think
8 it's pretty well-known.

9 There was a request to strike the
10 term "moderate" from the indication, add a
11 maximum daily dose, and add a maximum duration
12 of 90 days.

13 The indication was changed to talk
14 about patients severe enough, correct?

15 A. 2014 --

16 Q. Yeah.

17 A. -- a little afterwards.

18 Q. A little afterwards?

19 A. That's correct.

20 Q. But the FDA rejected the idea of
21 adding a maximum daily dose or a maximum
22 duration, correct?

23 A. FDA's thinking is, I think,
24 discussed later in the letter.

1 Q. Okay. So the letter sets forth
2 FDA's thinking on these issues, correct?

3 A. Correct.

4 Q. And, in fact, the FDA, through
5 today, has not been willing to have a maximum
6 daily dose or a maximum duration of 90 days for
7 continuous use?

8 MR. RAFFERTY: Object to the form.

9 A. Yeah. FDA probably is a little --
10 I mean, on this, I mean -- I mean, that's
11 correct, because it could not identify -- FDA
12 felt it could not identify the threshold.

13 Regrettably, that -- I think that's
14 the wrong burden, because it's not really --
15 FDA shouldn't have the responsibility of
16 identifying that. The manufacturer should do
17 that. But FDA did what it did here.

18 Q. And even today --

19 I think it's -- what is it, 7, the
20 label in 2018 that I gave you?

21 MR. RAFFERTY: That's the -- 7 is
22 the '96 label.

23 Q. So it must be 6. I'm sorry. It
24 says it right here, Exhibit 6, the 2018 label.

1 You can just look at it on the screen, if you
2 want.

3 A. Thanks, ma'am. It's here
4 somewhere.

5 Q. That's fine.

6 OxyContin is indicated for
7 management of pain severe enough to require
8 daily, around-the-clock, long-term opioid
9 treatment and for which alternative treatment
10 options are inadequate in adults and
11 opioid-tolerant pediatric patients 11 years of
12 age and older who are already receiving and
13 tolerating a minimum daily opioid dose of at
14 least 20 milligrams oxycodone orally or its
15 equivalent.

16 Correct?

17 And then it's under the Limitations
18 of Use where they added in 2018 language,
19 Because of the risk of addiction, abuse, and
20 misuse with opioids even at recommended doses
21 and because of the greater risk of overdose and
22 death with extended-release opioid
23 formulations, reserve OxyContin for use in
24 patients for whom alternative treatment options

1 are ineffective, not tolerated, or would be
2 otherwise inadequate to provide sufficient
3 management of pain.

4 Correct?

5 A. Correct.

6 Q. Okay. And even today, it does not
7 limit use of OxyContin to any particular
8 disease state, correct?

9 A. Because there's no substantial
10 evidence to support that.

11 Q. And it doesn't limit -- it
12 certainly doesn't limit OxyContin to use in
13 cancer pain, correct?

14 A. That's correct.

15 Q. And it doesn't say that it can't be
16 used in any number of underlying disease
17 conditions if the doctor deems the pain severe
18 enough to require daily, around-the-clock,
19 long-term opioid treatment, correct?

20 A. No. Keep on reading.

21 Q. And for which alternative treatment
22 options are inadequate, correct?

23 A. Correct. It has to meet all those
24 requirements today.

1 Q. And, in fact, that was always the
2 case, that it wasn't meant to be a first-line
3 therapy?

4 A. That was not what your company --
5 that's not what your company's marketing plans
6 reflect.

7 Q. Well, in fact, it was -- that is
8 how it was discussed.

9 A. No. That -- the one to start with
10 and the one to stay with?

11 Q. As an opioid. As an opioid. Not
12 as the first pain medication.

13 A. You try to push out -- your company
14 pushed out step two, the combinations. You
15 wanted -- you wanted it both ways. You wanted
16 it for -- to push out the combinations, and you
17 wanted the severe. And it was never supposed
18 to be used before -- the combinations, it was
19 never supposed to be used for the PRN.

20 Q. Do you know what --

21 A. And it certainly wasn't supposed to
22 be used at the kind of doses that it ended up
23 being used at.

24 Q. Do you know what percentage of

1 patients who used OxyContin were not naive to
2 opioid therapy?

3 A. I don't think I -- I don't think I
4 know that number.

5 Q. Okay. So --

6 A. Happy to see if I can find it.

7 Q. In actual practice, you don't know
8 what percentage of patients in the last ten
9 years who took OxyContin actually had taken
10 another opioid first?

11 A. I don't -- sitting here today, I've
12 not done that analysis.

13 Q. And sitting here today, do you know
14 what percentage of the market for all opioids
15 OxyContin was at any point in time?

16 A. Oh, yes. I have very specific -- I
17 can -- I can if you want to sit --

18 Q. What was it?

19 A. I have to get it for you. I don't
20 have it in my head, but I have it right in
21 front of me. Just give me a minute, and I will
22 get it for you.

23 Let me get my -- sorry.

24 Q. Where is it in your report?

1 A. Well, just give me a second,
2 please.

3 So if you look at -- let's just
4 see -- OxyContin, 2009, \$3 billion --
5 3 billion? Yeah, I think so. 2009 --

6 Q. Sir, I wasn't asking you --

7 A. -- 46 percent.

8 Q. You think that OxyContin was
9 46 percent of the market for prescription
10 opioids?

11 A. It was 46 percent of the
12 extended-release opioid market.

13 Q. And where are you getting that data
14 from?

15 A. Mallinckrodt TI-001191114.

16 Q. Okay. Do you know if that's ever
17 what the FDA has used as its numbers?

18 A. I haven't asked -- I have --

19 Q. Do you know if that's what NSDA --
20 the NSDA uses as its numbers?

21 A. I have to double-check on -- those
22 are the only --

23 Q. This is in your report in the
24 Mallinckrodt section?

1 A. No. This -- this is cited in a
2 document that's cited in my report.

3 Q. What's the -- what is the Bates
4 number on the document that you're using?

5 A. The page number, you can --

6 Q. The Bates number.

7 MR. RAFFERTY: He just read it.

8 A. Here, you can it put on -- and turn
9 it over. One is product sales, and one is
10 prescriptions, so you have a record of it. If
11 you turn it over, you'll see the --

12 Q. Is this your -- what is this page?

13 A. It's a page out of the document.

14 Q. All right. All right. It's
15 just -- I will just read the Bates number,
16 MNK-TI-0001191114. Okay.

17 A. And here. While you're at it,
18 here's your long-acting opioid market prior to
19 2009. You can have that.

20 Q. This is -- you just passed me a
21 document that is not Bates numbered but that
22 talks about long-acting total Rx trends?

23 A. Right.

24 Q. Okay.

1 A. And that's a -- that's a native
2 that I printed out.

3 Q. Okay. Do you know what the source
4 of this is?

5 A. I'm sure it could be searched.

6 Q. This is not --

7 A. It's in the database.

8 Q. This is not market percentage,
9 which was my question.

10 A. No -- no, but it give -- it
11 gives -- certainly gives you the two major
12 players at that point in time.

13 Q. I just asked you market percentage.

14 A. Well, you have that on the other
15 document.

16 Q. Okay. And that's what you think
17 the right answer is?

18 A. No. I'm telling you what -- I
19 mean, that's the data that I have. You asked
20 me for data, and I'm giving you the data that I
21 have.

22 Q. Do you know what topic areas were
23 covered in the launch materials -- what -- what
24 were themes covered or what the launch material

1 for OxyContin looked like?

2 A. I certainly read the launch plans
3 for those.

4 Q. I mean the sales aid, the visual
5 aids.

6 A. What I have in my head is the
7 launch plan. You'd have to refresh -- I'd have
8 to refresh my memory on --

9 Q. Do you know what --

10 A. -- on the aid.

11 Q. You can't remember what the visual
12 looked like or what any of the particular
13 product claims were?

14 A. What's in my head right now is the
15 launch plan.

16 MS. FREIWALD: Okay. And I'm just
17 going to mark as Exhibit 10 a letter
18 from the FDA in March of '96, Bates
19 number PPLP000614887.

20 (Exhibit Kessler-10 marked for
21 identification and attached to the
22 transcript.)

23 MS. FREIWALD: I'm happy to give
24 you a copy, Troy, later. I just -- in

1 the interest of time --

2 MR. RAFFERTY: Do you have a
3 copy -- I'm sorry. Do you have a copy
4 of the visual aid?

5 MS. FREIWALD: I can give it to you
6 later. I just, in the interest of --

7 MR. RAFFERTY: I mean for
8 Dr. Kessler.

9 MS. FREIWALD: In the interest of
10 time, the letter from the FDA --

11 There's something --

12 MR. RAFFERTY: I think -- well, the
13 thing's coming down, but I think --

14 MS. FREIWALD: Yeah, it's coming
15 down a little bit.

16 MR. RAFFERTY: -- per the
17 protocol --

18 Q. So this letter --

19 MR. RAFFERTY: Let me just state an
20 objection.

21 I think, per the protocol, if
22 you're going to ask the witness about --
23 about documents, it is incumbent to have
24 copies for the witness and for opposing

1 counsel.

2 MS. FREIWALD: I'm asking him --

3 You're right. I should have a copy
4 of this for you, and I will give it to
5 you.

6 BY MS. FREIWALD:

7 Q. But in the interest of time, this
8 letter is in response to Purdue Frederick's
9 March 8, '96 request for comments on a revised
10 OxyContin launch visual aid.

11 The Division of Drug Marketing,
12 Advertising, and Communication (DDMAC) has
13 reviewed the visual aid and has no objections
14 as proposed.

15 Did I read that correctly?

16 A. You did. You're refreshing my --
17 my memory is coming back.

18 Is this the steps assigned to this
19 visual aid?

20 Q. So do you -- did you go through --

21 A. Yes.

22 Q. -- in your report anywhere a
23 discussion of the communications with FDA
24 around the launch-related materials?

1 A. In detail.

2 Q. Where is that in your report?

3 A. I could -- it's certainly the --
4 the back and -- I have -- let me double-check.
5 It's certainly stuff that I reviewed that I
6 have in my head, because I know exactly what
7 Curtis was saying and what was said. It's
8 certainly in my reliance list, I am sure.

9 Q. And after -- there was dialogue
10 between the agency and Purdue with regard to
11 the substance of those materials. You remember
12 that?

13 A. About four or five back-and-forths.

14 Q. And the agency required certain
15 changes in those materials; do you recall?

16 A. No. What I -- I think would be
17 fair to say was that Curtis said specifically
18 he saw -- he was opposed to the drug being
19 used, in essence, as step two -- let me just
20 finish, please.

21 He was opposed to the drug being
22 used as step two, and I think there was a
23 compromise worked out, if you look at some fine
24 language, about step two in the final visual

1 aid.

2 But that was not what Curtis had
3 asked the company certainly earlier on, but the
4 company kept on coming back.

5 Q. And there were other issues that
6 were discussed as well in the visual aid beyond
7 just the step two. Do you remember that?

8 MR. RAFFERTY: I am going to object
9 to any further questions on documents
10 that you're not willing to provide to --

11 MS. FREIWALD: I'm asking --

12 MR. RAFFERTY: Excuse me. You can,
13 you know --

14 MS. FREIWALD: There's no speaking
15 objections. Just object to the form and
16 foundation.

17 MR. RAFFERTY: No. I'm going to
18 instruct him not to answer --

19 MS. FREIWALD: And you don't have
20 to -- well, you don't have the --

21 MR. RAFFERTY: -- any more
22 questions on documents that you're not
23 going to be, per the protocol, willing
24 to share with the witness.

1 MS. FREIWALD: Oh, for -- you --

2 MR. RAFFERTY: "You" what?

3 MS. FREIWALD: You don't even want
4 to go there with me, the number of
5 depositions I've sat through with
6 you where you didn't want to put a
7 document in front of --

8 MR. RAFFERTY: You haven't even
9 been in a deposition here --

10 MS. FREIWALD: Okay.

11 MR. RAFFERTY: -- with me.

12 Q. I'm asking, it's not in your
13 report?

14 MR. RAFFERTY: Let the record
15 reflect that's not true.

16 MS. FREIWALD: In other litigation.

17 Q. The launch-related materials are
18 not discussed in your report, are they?

19 A. Hold -- hold on one second, please.

20 MR. RAFFERTY: Here. Here's a copy
21 of the document, Doctor.

22 THE WITNESS: Thank you. Thank
23 you.

24 A. Here it is. I'm sorry.

1 Just give me -- give me a second.

2 Let me just get my -- my computer online.

3 Sorry. Here it is.

4 So I -- I believe I put together --

5 I mean, let me just -- can I see the material,
6 the --

7 Q. I'm really just asking, in the body
8 of your report where you're discussing Purdue
9 and the disconnect that you've described
10 between what was in the label and what the FDA
11 knew about the promotion, the launch materials
12 went through several back-and-forths with the
13 agency, correct?

14 A. And I have that all here, yes.

15 Q. Okay. And, ultimately, the agency
16 said that they -- The Division of Drug
17 Marketing, Advertising, and Communication has
18 reviewed the visual aid and has no objections
19 as proposed.

20 Correct?

21 A. That was what was written at that
22 time.

23 MS. FREIWALD: Okay. Let's take a
24 break.

1 How much --

2 Let's take a break. I want to look
3 at the time and see what we're going to
4 do.

5 VIDEO OPERATOR: 6:04, we are off
6 the video record.

7 (Recess from 6:04 p.m. until
8 6:23 p.m.)

9 VIDEO OPERATOR: 6:23, we are on
10 the video record.

11 (Exhibit Kessler-11 marked for
12 identification and attached to the
13 transcript.)

14 BY MS. FREIWALD:

15 Q. Doctor, you've talked about
16 promotional activities pre-2003 quite a bit.

17 I don't think that your report
18 references the corrective action that Purdue
19 took in conjunction with the FDA following the
20 warning letter in 2003, and I just want to see
21 if we can agree that this is, in fact, that
22 correction letter. Correct?

23 A. I would agree with that.

24 MR. RAFFERTY: Object to the

1 preamble.

2 Q. And it's Exhibit -- tell me what
3 exhibit I marked it as.

4 A. 11, ma'am.

5 Q. Exhibit 11. Thank you.

6 And it states that -- it
7 references, earlier publication of a journal
8 contained advertisement for OxyContin that was
9 the subject of a warning letter from the FDA in
10 January 2003 and that the company was accused
11 of violating certain provisions and that this
12 is a corrective letter.

13 And, consequently, we direct you
14 the safety information, information about
15 risks...

16 And then it includes a copy of
17 the -- of the box warning language, correct?

18 A. Correct.

19 Q. And -- and did you look to see how
20 widely this letter was distributed?

21 A. I didn't -- I don't know exactly
22 how many copies were sent.

23 Q. And did you also look at the fact
24 that there was corrective advertising that was

1 run in the same journals where the ads were?

2 A. I believe I know that.

3 Q. And do you -- do you know the
4 length of time of that corrective advertising
5 was discussed with the FDA and agreed to with
6 the FDA?

7 A. It would be, yes.

8 Q. And nobody at FDA ever thought that
9 the corrective promotion after the 2003 letter
10 was inadequate?

11 A. Incorrect.

12 Q. Is there any document you can find
13 where the FDA said, You're not -- you, Purdue,
14 are not engaging in the corrective behavior
15 long enough or broadly enough?

16 A. Not with reference to that, but I
17 interpreted your question differently.

18 Q. Okay. And, in fact, there's --
19 you -- I assume that, sitting here today,
20 you're not able to say how doctors interpreted
21 this corrective ad, how many of them who got
22 this letter even had seen the ad that the FDA
23 had an issue with in the first place?

24 MR. RAFFERTY: Object to the form.

1 A. I don't recall seeing recall
2 surveys of doctors on this.

3 Q. Okay. And you don't have any data,
4 sitting here today, about how many doctors in
5 January of 2003 who actually saw the ad
6 continued to prescribe OxyContin over the next
7 decade and a half?

8 A. Correct.

9 Q. And sitting here today, you don't
10 even have any information about how many
11 doctors who saw the original problematic ad
12 continued to prescribe OxyContin over the next
13 decade and a half?

14 A. I don't have that analysis.

15 Q. Okay. And do you know -- we've
16 spent a lot of time on call notes. Do you know
17 what percentage of the total calls in Ohio
18 you've excerpted from -- in your report?

19 A. No, I don't know that.
20 Specifically, I don't.

21 Q. Okay.

22 A. They are what they are.

23 Q. Do you know how many calls that
24 were made from 2007 to 2017 would have

1 delivered messages that were different from the
2 ones that you have in 2000- -- mostly in 2003
3 and earlier?

4 A. I don't have that quantitative -- I
5 didn't do that kind of -- the quantitative
6 analysis.

7 Q. And -- and do you know what sales
8 reps were discussing with doctors as label
9 changes were being made about the new labeling
10 language?

11 A. There are different call notes that
12 say different things.

13 MR. RAFFERTY: Object to the form.

14 Q. And did you look at any of the
15 abuse deterrent materials that the company put
16 out starting in 2000 and going up through 2017?

17 A. Yes.

18 MR. RAFFERTY: Object to the form.

19 Q. You don't -- do you cite in the
20 actual body of your report materials such as,
21 Protecting your practice?

22 MR. RAFFERTY: Object to the form.

23 A. I'm sorry. I thought you were
24 talking about abuse-deterrent formulation.

1 Q. No.

2 A. I apologize, ma'am.

3 Q. No.

4 A. I misinterpreted your question.

5 Q. Okay. Did you look, in call notes
6 or otherwise, for how many doctors in Ohio
7 received information from Purdue about,
8 Protecting your practice, or, Protecting your
9 patient from abuse?

10 A. I saw certain campaigns on that,
11 but I don't have the quantitative information.

12 Q. And you didn't look at call notes
13 to see how many times those messages were
14 delivered?

15 MR. RAFFERTY: Object to the form,
16 misstates his testimony.

17 A. I certainly looked at call notes
18 and read many call notes.

19 Q. Can you -- can you tell me -- you
20 didn't excerpt any of those call notes in your
21 report?

22 A. About, Keep the medicine safe?

23 Q. Yeah.

24 A. No -- no, I did not, I don't think.

1 Q. Okay. Do you --

2 A. I mean, I've got to go back and
3 check the -- I mean, the -- sorry. There
4 may -- there may be call notes that are
5 referenced in the schedules that reference
6 that, because there's multiple issues, but I
7 did not track specifically that issue.

8 Q. Did you track the number of
9 abuse-deterrent prescription pads that were
10 given out for free by Purdue in the counties in
11 Ohio or nationally during this time period?

12 A. I was aware of that, but I don't
13 have the -- somewhere, there may be a
14 quantitative in some of the reliance, but I
15 don't have that on top of my head.

16 Q. Did you track the number of
17 educational efforts that were made through
18 the -- what was referred to as the LELE program
19 by Purdue?

20 A. I did not track that specifically.

21 Q. Do you know what the LELE program
22 was?

23 A. I'd have to review that. Sitting
24 here, I'm -- it's not top of mind.

1 Q. Did you track the dissemination of
2 information on, Protecting your medicine
3 cabinet that was given to doctors to give to
4 patients about keeping their -- their drugs
5 safe?

6 A. I didn't track that in any -- I'm
7 aware of those campaigns. I've seen those
8 slides, those campaigns, those brochures. I
9 don't have the quantitative information.

10 Q. Do you know how much money or how
11 many resources the company expended to get that
12 information out to doctors over a decade and a
13 half?

14 A. I do have specific promotional --

15 Q. I'm not asking about promotional
16 dollars generally. I'm asking with regard to
17 those efforts to speak to -- of mitigating
18 abuse.

19 A. I was going to say, I have specific
20 dollars with regard to specific activities
21 here, if you'd like. It may be on the list.
22 Just give me -- if you'd like me to give it you
23 to --

24 Q. If it's -- if you think it's

1 referenced in your material somewhere, then
2 I'll look for it later, because I have very
3 little time.

4 A. I can give you -- I can just simply
5 give you a Bates number.

6 So if you look at -- look at
7 PPLP003409960, that's the promotional
8 incremental -- those are the activities that
9 are spent, and I'm not sure I see that one
10 broken out in the ROI on those.

11 Q. Okay. And do you know how much the
12 company dedicated to assisting with better PDMP
13 programs?

14 A. I don't --

15 Q. Did you track those efforts?

16 MR. RAFFERTY: Which question do
17 you want him to answer?

18 Q. Did -- did you track in any way,
19 dollars, effort -- I'll ask the question very
20 broadly -- PDMP investments?

21 A. So I have -- I have -- I didn't
22 track myself, but I do have information on what
23 the company tracked on a number of programs and
24 what the dollar spend was and the incremental

1 total Rx that it yielded to.

2 Q. Am I going to find anything
3 specifically on PDMP efforts?

4 A. We'd have to go through the
5 reliance list. I don't see in this -- I don't
6 see that program specifically, the contribution
7 by promotional challenge. I don't see that one
8 listed in this chart.

9 Q. You didn't -- you didn't discuss
10 it? That would be an effort to reduce abuse
11 and diversion, and you didn't discuss that in
12 your report?

13 MR. RAFFERTY: Objection to form.

14 A. Because I'm pretty sure it's in my
15 reliance list, because those activities I'm
16 certainly aware of and I have reviewed.

17 Q. Do you -- do you know how much the
18 company invested in other means of preventing
19 diversion, whether it's helping track illicit
20 drugs coming in from Mexico, helping with
21 placebo pills, to help law enforcement engage
22 in sting operations? Did -- did you analyze
23 any of those efforts by the company?

24 A. I looked at those -- I looked at a

1 number of different programs that were focused
2 on that at different points in time, but I
3 don't have a quantitative estimate.

4 Q. And is there any method that you
5 had for putting that into a matrix for judging
6 what -- how information you thought was
7 misleading was balanced against information the
8 company was putting out about abuse and misuse
9 and proper prescribing and proper monitoring?

10 A. Yes.

11 MR. RAFFERTY: Object to form.

12 Q. What would the -- what is the
13 matrix that you have?

14 A. You can look at the incremental TRx
15 by promotional activity, and you can see the
16 trends in total number of pills.

17 Q. So is it your testimony that as
18 long as prescriptions weren't declining, that
19 the -- that doctors weren't understanding the
20 risk?

21 MR. RAFFERTY: Object to the form.

22 A. I'm sorry. I don't understand your
23 question.

24 Q. I'm -- is it your testimony that if

1 prescriptions weren't declining, that proves
2 that doctors failed to understand the risk?

3 MR. RAFFERTY: Object to the form.

4 A. Not exactly.

5 Q. Well, I'm asking you if there is --
6 you've testified that the label says what it
7 says, and it included information we've gone
8 through about abuse, misuse, addiction,
9 tolerance, et cetera.

10 But you said, if I understand your
11 testimony, It's not about the label; it's about
12 the promotional messages.

13 And I'm asking you, did you do
14 anything to attempt to characterize or weigh
15 the impact of the promotional -- promotional
16 messages against all the efforts that were
17 being made to communicate risk, threat of
18 diversion, threat of misuse, needing to monitor
19 your patient, needing to make sure that you
20 were prescribing for the correct patient,
21 needing to make sure that the patient was
22 guarding their medicines?

23 A. Yes.

24 MR. RAFFERTY: Objection.

1 Q. Where is that --

2 MR. RAFFERTY: Objection, compound
3 and long.

4 Q. Where is that in your report?

5 A. I mean, it's -- the report
6 discusses the increased use for a broadened
7 range of indications.

8 Q. So is it your testimony that the
9 fact -- that increase in prescription is proof
10 of either wrongdoing or failure to provide
11 information to doctors that was accurate?

12 A. The use of the drug in
13 indications -- in broad range of indications
14 beyond where it was appropriate shows that
15 those -- those things were not working.

16 Q. Is it -- what have you done to rule
17 out the possibility that doctors understood the
18 risk but made a decision to prescribe the
19 product?

20 MR. RAFFERTY: Object to the form.

21 A. That -- that shift -- if you look
22 somewhere here, if you look at the shift in --

23 Well, because if you look at
24 Purdue's documents itself, you see that the

1 increased volume -- and it's quantitated in a
2 number of your client's documents about the
3 promotional sensitivity, and that was not
4 independent of that.

5 The promotion -- this was
6 promotionally sensitive, that increase, and
7 there was a shift.

8 Q. All products have some promotional
9 sensitivity. That doesn't prove --

10 MR. RAFFERTY: Were you done,
11 Doctor?

12 Q. -- that marketing was improper.

13 So what I want to know is, what
14 have you done -- what methodology have you used
15 that anybody could recreate to say that any
16 increase in prescriptions or continuation of
17 writing of prescriptions was because doctors
18 didn't understand the potential risk profile,
19 as opposed to because they understood it, but
20 they were making a considered decision for
21 their patients?

22 MR. RAFFERTY: Object to the form.

23 A. Well, they were making that
24 decision based on promotional sensitivity.

1 Q. As opposed -- other than your
2 say-so, how does one prove that?

3 MR. RAFFERTY: Object to the form.

4 A. So just give me one second. Hold
5 on a second. There is -- hold on a second.
6 Hold on a second.

7 Q. Sir, I'm looking for --

8 A. No, no. I --

9 Q. -- a methodology. I'm looking --

10 A. I said the company's own documents,
11 and I will -- can I give -- I have a sheet her,
12 and I just -- hold on one second. Let me just
13 see.

14 I mean, there are documents that --
15 and I will find them for you; they're here --
16 that show that the company tracked specifically
17 what increased prescriptions were due to its
18 promotional activity.

19 Q. Sir, there's -- I understand that.
20 You've made that very clear.

21 But there are hundreds of
22 prescription drugs that are promotionally
23 sensitive. That doesn't mean that they're
24 being promoted incorrectly. So what I want to

1 know is -- or that doctors misunderstand their
2 risk profile.

3 So what I want to know is what you
4 have done that another expert could reproduce
5 or test that establishes that the continued
6 prescription of the drug is because of a
7 failure to understand the risk/benefit profile.

8 MR. RAFFERTY: Object to the form.

9 Move to strike the editorial comments.

10 And it's been asked and answered.

11 A. The company's -- the company's
12 documents -- the company's marketing plans and
13 its -- the company's marketing plans, its
14 marketing budgets, its ROI documents, and its
15 return on investment for that promotion and
16 what those marketing efforts -- as well as the
17 shift.

18 I mean, back -- back in 1980,
19 oxycodone was not a drug of choice. That
20 shifted after the promotional activity. I
21 think there's no question, we went from a drug
22 not of choice for chronic use in the medical
23 establishment to one that was.

24 Q. Do you -- do you agree with me,

1 sir, that there are --

2 MR. RAFFERTY: Were you finished?

3 Q. -- drugs that were not once
4 prescribed that are now prescribed commonly?

5 This is not the only place where there has been
6 shift in prescribing practices?

7 MR. RAFFERTY: Object to the form,
8 vague, and overly broad.

9 A. Yes, but the -- but the --

10 Q. Yes. The answer is "yes," right?
11 There have been shifts in prescribing practices
12 with regard to multiple disease states,
13 correct?

14 MR. RAFFERTY: Answer the question
15 how you want, Doctor.

16 Q. Yes?

17 MR. RAFFERTY: Let him finish his
18 answer.

19 A. There are shifts in time in
20 prescribing, correct. This shift toward higher
21 doses and changing -- your -- your -- the
22 documents themselves, your company takes
23 credit, I mean, for changing the way pain was
24 treated with opioids.

1 We now know that is wrong, that
2 method is wrong. The current label, right,
3 recognizes that that method was wrong.

4 Q. One more question.

5 Do you know what happened to
6 prescribing rates for OxyContin after 2010?

7 A. I'd have to get -- specifically,
8 I'd have to look exactly at which years. As
9 the abuse-deterrent formulation came on, other
10 drugs took its place.

11 Q. So when the abuse-deterrent
12 formulation came on, if the record reflects
13 there was a decline, would you -- would you
14 then say -- if you're going to say that
15 increase is a result of improper understanding
16 of the drug, will you say that the decline is a
17 result of proper communication, proper
18 understanding of risk?

19 MR. RAFFERTY: Object to the form.

20 A. No.

21 MS. FREIWALD: Honestly, sir, I've
22 got easily three or four more hours of
23 questions for you because I have not
24 been able to put in front of you most of

1 the documents that you put in your
2 report with regard to my client and I
3 haven't been able to get answers other
4 than speeches.

5 But I've got a whole bunch of
6 co-defendants, and I don't have a choice
7 at this point other than to -- other
8 than to pass the chair.

9 So I'm going to do that, but I want
10 to be clear on the record that I'm doing
11 that with objection and state that I
12 simply have not had the time to cover
13 even three-quarters of your generic
14 opinions, let alone probably more than
15 about a third of your Purdue opinions.

16 MR. RAFFERTY: Are you finished?
17 Because that is utterly untrue.

18 And so if we're stating stuff for
19 the record, at one point we took a
20 30-minute break so you could prepare for
21 the deposition.

22 Now, your failure to prepare for
23 depositions --

24 MS. FREIWALD: Oh, god.

1 MR. RAFFERTY: -- and your failure
2 to ask the -- and you're asking
3 open-ended questions. And if you're
4 going to ask open-ended questions,
5 you're going to get an answer.

6 MS. FREIWALD: I think --

7 MR. RAFFERTY: And I'm sorry that
8 you didn't like the answer -- excuse me.
9 Let me -- I let you give your rant.

10 So the fact of the matter is, is
11 that he answered the questions you
12 asked, and when you asked a narrow
13 question, he gave you a narrow answer.
14 When you asked a broad question, he gave
15 you a broad answer. That's the simple
16 facts, and the record will reflect that.

17 So if -- we spent, you know, a good
18 hour just reading documents. So you
19 know, if that's how you wanted to spend
20 your time, that's how you spent your
21 time.

22 MS. FREIWALD: I think the record
23 will speak for itself and, I think, will
24 also speak for the fact that with a

1 300-page report and 100 pages of opinion
2 as to my client alone, two hours of
3 questioning is plainly inadequate.

4 MR. RAFFERTY: Well, that's --

5 MS. FREIWALD: So we're going to
6 pass the witness.

7 MR. RAFFERTY: -- that's between --
8 that's between you and your
9 co-defendants.

10 MS. FREIWALD: Okay.

11 MR. RAFFERTY: The Court gave you
12 14 hours.

13 How much time are we on the record?

14 VIDEO OPERATOR: That's 21 minutes
15 added to the 6:39.

16 MR. RAFFERTY: So we're just over
17 seven.

18 All right. I think, quite frankly,
19 instead of shifting over, if everybody
20 wanted to end at seven, I don't know
21 that it makes a bunch of --

22 MS. FREIWALD: I think we need to
23 go longer.

24 MR. DAVIS: Can we go off for just

1 one second?

2 MS. LEVY: Can we go off the
3 record?

4 MR. DAVIS: We have a -- I have a
5 suggestion.

6 MR. RAFFERTY: Uh-huh, sure. I
7 love suggestions.

8 MS. LEVY: Off the record?

9 VIDEO OPERATOR: Off the record?

10 MR. RAFFERTY: Yeah.

11 VIDEO OPERATOR: 6:44, we are off
12 the video record.

13 (A discussion was held off the
14 record.)

15 VIDEO OPERATOR: 6:46, we are on
16 the video record.

17 EXAMINATION

18 BY MR. BORANIAN:

19 Q. Steven Boranian for Defendant
20 AmerisourceBergen Drug Corporation, which is a
21 distributor, Dr. Kessler.

22 You said earlier today that you
23 have no opinions with regard to distributors,
24 and that's still true now, correct?

1 A. Correct.

2 Q. Now, you've listed the names of all
3 the defendants in this case in your report, I
4 think at paragraph 10. Is that right?

5 A. I believe that's correct.

6 Q. So I have two questions, Doctor.

7 Have you formed any opinions with
8 regard to any of the distributors who are
9 listed as defendants in your report?

10 A. Nothing that I will give at trial,
11 no.

12 Q. Well, you predicted my next
13 question, Doctor, which is, do you intend to
14 appear at trial and give opinions with regard
15 to any distributor listed in your report?

16 A. Whether I appear at trial is simply
17 counsel and the Court. I -- I --

18 What was the first question? What
19 was -- what was the full question? I'm sorry.

20 Q. The question is, do you intend to
21 appear at trial and offer any opinions with
22 regard to distributors?

23 A. If I appear at trial, I do not
24 intend to offer any opinions with regard to

1 distributors.

2 MR. BORANIAN: Thank you, Doctor.

3 THE WITNESS: Thank you, Counselor.

4 MR. BORANIAN: I think we can just
5 stay on the record.

6 MR. RAFFERTY: Is that going to be
7 the same for all the other distributors?

8 Oh, okay. I was going to say,
9 maybe we can just get him to say --

10 EXAMINATION

11 BY MR. LAVELLE:

12 Q. Good afternoon, Doctor. John
13 Lavelle from Morgan, Lewis, and I'm
14 representing Rite Aid -- actually, Rite Aid of
15 Maryland, doing business as the Maryland -- as
16 the Mid-Atlantic Distribution Center.

17 Are you aware that there are a
18 number of pharmacy entities that are named as
19 defendants in this litigation?

20 A. I am, sir.

21 Q. And I want to ask you some
22 questions about those pharmacies and
23 specifically about Rite Aid, CVS, Wal-Mart,
24 Walgreens, and Giant Eagle.

1 A. Okay.

2 Q. Can we refer to those as the retail
3 chain pharmacies?

4 A. Fair.

5 Q. Doctor, do you have any opinions,
6 as we sit here today, that you intend to offer
7 with respect to the retail chain pharmacies?

8 A. At trial, no.

9 Q. You don't have any in the report
10 that you've served; is that correct?

11 A. That's correct.

12 Q. And you don't intend to serve -- to
13 offer any opinions at trial --

14 A. Correct.

15 Q. -- concerning any of those retail
16 chain pharmacies?

17 A. Correct.

18 MR. LAVELLE: Thank you, Doctor.

19 That's all I have.

20 THE WITNESS: Thank you, Counselor.

21 MR. RAFFERTY: That's it?

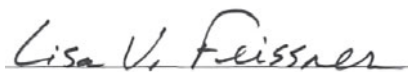
22 VIDEO OPERATOR: 6:49. We are off
23 the video record.

24 (Off the record at 6:49 p.m.)

C E R T I F I C A T E

I, Lisa V. Feissner, RDR, CRR, CLR,
Notary Public, certify that the foregoing is a
true and accurate transcript of the deposition
of said witness, who was first duly sworn by me
on the date and place hereinbefore set forth.

I further certify that I am neither
attorney nor counsel for, nor related to or
employed by, any of the parties to the action
in which this deposition was taken, and
further, that I am not a relative or employee
of any attorney or counsel employed in this
action, nor am I financially interested in this
case.



Lisa V. Feissner, RDR, CRR, CLR

Notary Public

Dated: APRIL 29, 2019

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate column on the errata sheet for any change made.

After doing so, please sign the errata sheet and date it.

You are signing it subject to the changes you have noted on the errata sheet, which will be attached to your deposition. You must sign in the space provided. The witness need not be a notary public. Any competent adult may witness your signature.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition may be deemed to be accurate and may be used in court.

1 WITNESS NAME: DAVID A. KESSLER, M.D.

DEPOSITION DATE: APRIL 25, 2019

2

3 ERRATA

4 PAGE LINE CHANGE REASON

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1 ACKNOWLEDGMENT OF DEPONENT

2

3 I hereby acknowledge that I have read
4 the foregoing deposition, pages 1 - 414, dated
5 April 25, 2019, and that the same is a true and
6 correct transcription of the answers given by
7 me to the questions propounded, except for the
8 changes, if any, noted on the attached Errata.

9

10

11 SIGNATURE:

DAVID A. KESSLER, M.D.

12

13 DATE:

14

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17 WITNESSED BY:

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19 DATE:

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	LAWYER'S NOTES		
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